



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/Fluid

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS

ACTION: Issuance of guidelines.

SUMMARY: The Department of Health and Human Services (“HHS” or “Department”) has established scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).

DATES: Effective January 1, 2020.

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SUPPLEMENTARY INFORMATION: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) will allow federal executive branch agencies to collect and test an oral fluid specimen as part of their drug testing programs. In addition, some agencies, such as the Department of Transportation, are required to follow the Guidelines in developing drug testing programs for their regulated industries, whereas others, such as the Nuclear Regulatory Commission (NRC), use the Guidelines as part of the regulatory basis for their drug testing programs for their regulated industries. The OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and

methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.

The OFMG provide flexibility for federal agency workplace drug testing programs to address testing needs and revise the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988. Since 1988, several products have appeared on the market making it easier for individuals to adulterate their urine specimens. The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine. For example, oral fluid collection devices and procedures have been developed that protect against biohazards, maintain the stability of analytes, and provide sufficient oral fluid for testing. Additionally, specimen volume is also much lower, saving time in collection and transport cost. Developments in analytical technologies have provided efficient and cost-effective methods with the analytical sensitivity and accuracy required for testing oral fluid specimens.

Federal agencies, MROs, and regulated industries using the OFMG will continue to adhere to all other federal standards established for workplace drug testing programs. The OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG).

Background

The Department of Health and Human Services, by authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and

technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858]. The revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on January 23, 2017 [82 FR 7920] with an effective date of October 1, 2017.

The Department published the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) in the May 15, 2015 Federal Register (80 FR 28054). There was a 60-day public comment period, during which 120 commenters submitted comments on the OFMG. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at <http://www.regulations.gov/>. All comments were reviewed and taken into consideration in the preparation of the Guidelines. The issues and concerns raised in the public comments for the OFMG are set forth below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Requirements for specimen validity testing

The Department requested comments on requirements for federal agencies to test all oral fluid specimens for either albumin or immunoglobulin G (IgG) to determine specimen validity. Four commenters agreed with the proposed requirements. Twelve commenters disagreed with the Guidelines as written, suggesting that specimen validity testing is not needed because all oral fluid collections are observed, collection procedures require visual inspection of the mouth by the collector and a 10-minute wait period, collection devices contain a volume indicator, and there is a limited volume of oral fluid collected and this volume is needed to complete confirmatory drug tests. One commenter expressed concern over the consequences of erroneous validity test results in relation to inappropriate cutoffs being set. One commenter questioned the proposed specimen validity testing analytes and cutoffs, and proposed that volume sufficiency be determined upon receipt at the laboratory. One commenter disagreed with the proposed IgG cutoff. One commenter disagreed that specimen validity testing should be performed on all specimens, and recommended performing specimen validity testing on a randomly chosen subset. This commenter also stated that specimen validity testing must be subjected to oversight by proficiency testing and blind sample testing programs. The Department has evaluated the comments and has revised the Guidelines to allow, but not require, specimen validity testing. The Department agrees that the OFMG collection procedures greatly minimize the risks of donor attempts to tamper with the specimen, and the volume indicator requirement for oral fluid collection devices should prevent collection of insufficient volume. To avoid prohibiting use of albumin and IgG tests, as well as other scientifically supportable oral fluid biomarker or adulterant tests that may become available, the Department is authorizing specimen validity testing upon request of the Medical Review Officer as described in Sections 3.1 and 3.5. All tests must be properly validated and include appropriate quality control samples in accordance

with these Guidelines. In response to commenters' concerns about expending the limited volume of oral fluid collected, it should be noted that HHS-certified laboratories currently performing specimen validity tests for non-regulated oral fluid testing use low volumes (i.e., 25 mcL for albumin tests, 15 mcL for IgG tests) that would not be expected to have a significant impact on a laboratory's ability to complete testing.

Proposed cutoff concentrations

Nineteen commenters submitted comments on the proposed drug test cutoffs. Some were general comments, while others concerned specific drug analytes. Cutoffs for marijuana tests are discussed in the following section, *Testing for Marijuana Use*. The comments and the Department's responses concerning cutoffs for other drug tests are described below.

Two commenters agreed with all proposed analytes and cutoffs. Two deferred setting cutoffs to HHS-certified laboratories. Three disagreed with all proposed cutoffs. Two of these commenters recommended retaining the cutoffs in the proposed Guidelines of April 13, 2004 (69 FR 19673). One of these commenters believes that the technology to detect analytes at these low levels is questionable and that these cutoffs will identify employees on prescribed medications. One commenter requested the basis for changing the cutoffs from those proposed in 2004. As described in the preamble to the proposed OFMG (80 FR 28054), the Department based the proposed cutoffs for each drug on information in public comments from the April 2004 proposed Guidelines, public responses to the June 2011 Request for Information (76 FR 34086), and the recommendations of a technical workgroup consisting of subject matter experts and representatives from various stakeholder groups (e.g., collection device and test kit manufacturers, oral fluid drug testing laboratories). The Department provided the recommended

cutoffs with supporting scientific information to the SAMHSA Drug Testing Advisory Board (DTAB) for review and discussion and, in the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, pages 28061-28065), included reasons for the proposed cutoffs for each drug, with references to supporting scientific studies. The Department has raised the cutoffs for some drug tests to address specific comments as described below. The Department concluded that no change is needed for other analytes. The cutoffs in Section 3.4 are supported by scientific studies, and are consistent with the goals of the federal workplace drug testing programs. The National Laboratory Certification Program (NLCP) Pilot Performance Testing (PT) Program has documented that laboratories are able to meet the Guidelines requirements using the cutoffs in Section 3.4.

One commenter agreed with the proposed initial test cutoff for cocaine, and recommended that a slightly lower cutoff be used for the confirmatory test. The Department did not find scientific evidence to warrant a change to the proposed confirmatory cutoff, which is the same as that proposed in 2004.

Five commenters disagreed with the proposed codeine and morphine cutoffs. Two commenters stated that the cutoffs are too low: one expressed concern over the technology to detect analytes at the proposed low levels and both noted that the change from currently used cutoffs will increase the number of initial test positives, thereby increasing costs. Two commenters stated that the Department has not supported changing from the cutoffs proposed in 2004 (i.e., 40 ng/mL for both the initial and confirmatory tests), which are currently used by the industry. One commenter indicated that their test data support a cutoff of 30 ng/mL for both the initial and confirmatory tests. In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, page 28063), the Department included reasons for the selected test cutoffs for each drug,

with references supporting those cutoffs. The Department is retaining the proposed cutoffs (i.e., 30 ng/mL for the initial test and 15 ng/mL for the confirmatory test) and is providing further explanation below to address the comments.

Reports in the literature provide information supporting lowering the morphine initial test cutoff from 40 to 30 ng/mL. In one dosing study with doses of 20 and 10 mg of morphine sulfate, morphine concentrations in saliva peaked at 0.5 hours at 37.8 ng/mL and 10.8 ng/mL, respectively, with detection times of 24 hours using a limit of detection (LOD) of 0.6 ng/mL.¹ In another report, morphine concentrations in oral fluid of treatment patients (n=4575) were reported to range from 2 to 3026 ng/mL with a median concentration of 49.8 ng/mL.² It was also found that 25% of the specimens contained morphine less than 13.5 ng/mL. These reports of short detection times and low concentrations of morphine in oral fluid also justify lowering the confirmatory cutoff for morphine to 15 ng/mL. The NLCP Pilot PT program has demonstrated oral fluid testing laboratories' abilities to meet codeine and morphine confirmatory cutoffs of 15 ng/mL using current testing technologies.

One commenter agreed with the proposed initial test cutoffs for oxycodone, oxymorphone, hydrocodone, and hydromorphone, but recommended that the same cutoffs be used for confirmatory testing. One commenter disagreed with all proposed cutoffs for these drugs, stating that the cutoffs are too low and will identify legitimate prescription users. The Department will retain the cutoffs as proposed. In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, pages 28064-28065), the Department included reasons for the selected test cutoffs for each drug, with references supporting those cutoffs. Considerable research and discussion were conducted regarding the complex issues surrounding the specification of each cutoff concentration. The Department solicited input from laboratories, reagent and device

manufacturers, subject matter experts, and the Food and Drug Administration (FDA). The cutoff concentrations are the outcome of the lengthy discussion process and represent the best approach currently available. Furthermore, the OFMG include the same requirements as the UrMG for Medical Review Officers to interview donors to determine whether there is a legitimate medical explanation for a positive test result, and to review documentation provided by the donor to support a legitimate medical explanation.

One commenter disagreed with the proposed 3 ng/mL initial test cutoff for 6-acetylmorphine (6-AM), stating that the proposed cutoff is higher than that currently used. As suggested by the commenter, and based on current 6-AM test methods and laboratory results from the NLCP Pilot PT Program, the Department has raised the proposed 6-AM initial test cutoff in Section 3.4 to 4 ng/mL (i.e., the same as proposed in 2004). The same commenter recommended a higher confirmatory test cutoff (3 ng/mL vs. the proposed 2 ng/mL), and noted that their data show that using an opiates cutoff of 30 ng/mL and a 6-AM confirmatory cutoff of 3 ng/mL identifies more positive 6-AM specimens than urine testing. The comparison of 6-AM positivity rates in urine and oral fluid does not support a change to the proposed confirmatory test cutoff. Studies have shown that 6-AM is statistically more likely to be detected in oral fluid than urine, regardless of the cutoff.^{3,4,5} The Department has retained the 2 ng/mL 6-AM confirmatory test cutoff proposed in 2015, primarily for enhanced sensitivity. Studies have shown that 6-AM concentrations between 1 and 3 ng/mL are detected in the study populations.^{2,3,6,7}

One commenter agreed with the proposed test cutoffs for phencyclidine (PCP). Three others disagreed, recommending that the Department use the 2004 proposed cutoffs (i.e., 10 ng/mL for both the initial and confirmatory tests). The Department has evaluated the comments and agrees with commenters that there is an insufficient scientific basis to warrant changes from the PCP

test cutoffs in the April 13, 2004 proposed Guidelines (69 FR 19673), which are currently used by many test manufacturers and laboratories. Therefore, the Department has raised the proposed cutoffs in Section 3.4 as follows: PCP cutoffs are 10 ng/mL for both the initial and confirmatory tests.

Six commenters disagreed with the proposed test cutoffs for amphetamines. Two of these commenters recommended that the Department use the 2004 proposed cutoffs (i.e., 50 ng/ml for both the initial and confirmatory tests). One recommended that the 2004 cutoff be used for the initial test; another recommended using the 2004 cutoff for the initial test and half of that concentration (25 ng/mL) as the confirmatory test cutoff. One commenter suggested cutoffs of 150 ng/mL or 120 ng/mL. One suggested setting cutoffs at 120 ng/mL or above to reduce the number of unverified positive initial tests. One commenter requested the basis for using different initial and confirmatory test cutoffs for methylenedioxymethamphetamine (MDMA).

The Department has evaluated the comments and agrees with commenters that, for amphetamines, there is an insufficient scientific basis to warrant changes from the initial test cutoffs in the April 13, 2004 proposed Guidelines (69 FR 19673), which are currently used by many test manufacturers and laboratories. Therefore, the Department has raised the proposed initial and confirmatory test cutoffs in Section 3.4 as follows: the initial test cutoff for amphetamines (i.e., amphetamine, methamphetamine, MDMA, and MDA) is 50 ng/mL, and the confirmatory test cutoff for each amphetamine analyte is 25 ng/mL.

Testing for Marijuana Use

The Department requested comments on several topics related to testing for marijuana use. Public comments and the Department's responses are described below. After reviewing the

comments, as well as the results of scientific studies published after the development of the proposed OFMG, the Department has decided to test for one marijuana analyte, delta-9-tetrahydrocannabinol (THC). THC is the primary psychoactive constituent (or cannabinoid) of the cannabis plant and is the primary intoxicant in marijuana. After careful consideration of all available evidence for THC in oral fluid, the Department has decided to retain the proposed 4 ng/mL initial test cutoff for THC in the final OFMG. Details regarding this decision are described below.

The capability of laboratories to test delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA) analyte using a cutoff of 50 pg/mL

One commenter agreed and four commenters disagreed that laboratories were currently capable of testing THCA in oral fluid using this cutoff. One commenter stated that laboratory instrumentation required for the analysis of THCA in oral fluid is widely available and can be added to routine laboratory testing. The commenter listed examples: two-dimensional gas chromatography/mass spectrometry (GC/MS), GC/MS/MS, and liquid chromatography (LC)/MS/MS. Three commenters disagreed, stating that it would require significant investment in more sensitive instrumentation. One commenter disagreed, stating they doubt the capabilities of the laboratories to consistently test for THCA with accuracy, sensitivity and validity. One commenter disagreed, stating that the number of laboratories with the experience in testing for THCA is limited. The Department has evaluated the comments and agrees that there is a limited number of laboratories currently testing for THCA in oral fluid. Only one commercial drug testing laboratory participating in the Oral Fluid Pilot PT program performed THCA testing. Furthermore, due to the concentration differences between THC (i.e., nanogram/milliliter or

ng/mL levels) and THCA (i.e., picogram/milliliter or pg/mL levels), immunoassays do not have sufficient cross-reactivity to enable use of a single assay for both analytes. Initial testing for both THC and THCA would require two separate immunoassay kits or use of alternative technology. No current immunoassay has been identified that is selective for THCA only. Laboratories planning to become HHS-certified to test federal agency oral fluid specimens may already have instrumentation for confirmatory testing that could be used as an alternate technology for initial testing, but may incur additional costs to develop and validate these new initial drug tests.

The validity of whether THCA can be established as an accurate, sensitive and valid marker for oral fluid testing to detect marijuana use and whether THCA should be used to extend the window of detection for marijuana use

Four commenters agreed with THCA as a test analyte. These commenters believe that analysis of THCA may prevent or minimize the risk of positive results due to “passive exposure” (i.e., a nonsmoker’s exposure to secondhand marijuana smoke). One commenter stated that if both THC and THCA analytes are required to be present to constitute a rule or policy violation, this would also eliminate protracted detection of THCA. The commenter suggested that if only one of the marijuana analytes is reported, it could be addressed as a safety concern. This commenter also opposed MROs requesting THCA testing as needed and, as an alternative, suggested requiring disclosure from the donor at the time of collection (i.e., the collector would ask the donor whether the donor had been exposed to marijuana recently and testing for THCA would be performed based on the donor’s answer). If the donor indicated no recent exposure, the donor has waived the right to a passive inhalation defense. One commenter recommended an agency or employer should have the option to choose either test (THC or THCA), providing

flexibility for employers' testing goals. One commenter noted that THCA testing, if included in the Guidelines, would be in conjunction with THC testing and expressed concerns including how to handle two test results (THC and THCA) that do not agree, additional costs, longer turnaround time, and handling of retests.

Six commenters disagreed with THCA as a test analyte. One commenter disagreed, suggesting solely testing for the active parent drug is one of the defining characteristics of oral fluid testing. Two commenters disagreed, suggesting THCA is not a reliable metabolite to be an appropriate marker for marijuana use. One commenter disagreed, stating that THCA is only present in oral fluid at very low levels. One commenter disagreed, suggesting that under realistic conditions of casual passive exposure and specimen collection where the collection occurs outside the exposure area, a donor would not test positive for THC at the currently used initial test (3 ng/mL) and confirmatory test (1.5 ng/mL) cutoffs. One commenter disagreed, stating that more research is needed before adding THCA to the Guidelines. One commenter disagreed, indicating that, for the majority of the time, no significant THC positives are reported for samples containing THCA alone. The commenter also stated that for THCA alone (in the absence of THC) to be detected as positive in the immunoassay, the level must be at least 1000 pg/ml, and that specimen volume is limited and should not be wasted for unnecessary tests.

The Department has evaluated the comments and decided to use THC as the sole initial and confirmatory test analyte for marijuana, with a 4 ng/mL initial test cutoff and a 2 ng/mL confirmatory test cutoff. This decision is supported by the reasons detailed below.

First, the Department is not aware of any scientific evidence to suggest that individuals would test positive for THC under the standards in these Guidelines as the result of incidental exposure to secondhand marijuana smoke. The preamble to the proposed OFMG, published on

May 15, 2015, provided information on THC and THCA results from studies of subjects who were passively exposed to marijuana smoke under a variety of exposure conditions.⁸⁻¹¹ These studies, detailed below, were conducted under conditions of extreme marijuana smoke exposure for several hours in enclosed spaces (i.e., heavy smoke in unventilated and ventilated conditions). The study data indicate that transient amounts of THC may be present in nonsmokers' oral fluid for a few hours (i.e., one to three), but only under those extreme conditions, meaning exposure to smoke from multiple cannabis cigarettes in an enclosed space for an extended time period.

One 2011 study tested nonsmokers in two Dutch coffeehouses where marijuana was being smoked.¹⁰ While some positive tests were obtained from the subjects, those samples were taken during a time of ongoing exposure to marijuana smoke in the coffeehouses, no subjects tested positive after returning for a final collection 12 to 24 hours after exposure. It should be noted that at the time of this notice's publishing, recreational and/or medical marijuana use is not permitted in places of public accommodation under either state or federal law. While this study demonstrated the types of THC oral fluid concentrations that could be obtained during exposure to secondhand marijuana smoke, the study is not directly applicable to Federal drug testing because the positive specimens collected in this study were collected during ongoing exposure to secondhand marijuana smoke, which does not approximate federal drug testing collection conditions.

A more recent study exposed nonsmokers to extreme levels of marijuana smoke under controlled conditions.^{12,13} The extreme exposure in this 2015 study consisted of three different one-hour sessions in which nonsmokers were enclosed in a sealed room with six smokers who smoked cannabis cigarettes almost continually through each session. The room was a specially

constructed sealed Plexiglas chamber (10 ft. by 13 ft. with a 7-ft. ceiling). Nonsmokers and smokers were seated around a table in alternating seats and the nonsmokers were continually exposed to heavy amounts of marijuana smoke. In two sessions, there was no air flow (i.e., air conditioning was turned off) and in one session, the air conditioning was turned on. Heavy marijuana smoke was present in each session and the smoke caused eye irritation in the two non-ventilated sessions. Because of the extreme smoke conditions, most participants elected to wear eye goggles to reduce eye irritation. In this study, 3 of the 6 nonsmokers were negative directly after the exposure concluded (0 hours) and 4 of 6 were negative at 0.5 hours.

Some of these subjects (nonsmokers) also reported drug effects that were approximately 25% of the smokers' responses (i.e., self-reported effects on a visual analog scale). The nonsmokers also exhibited detectable levels of performance impairment on some behavioral/cognitive assessments. Therefore, a reasonable donor in a safety sensitive position who is aware that he or she is in an enclosed environment with heavy levels of secondhand marijuana smoke should understand that he or she is very likely to experience the effects of inhaled marijuana smoke if he or she remains in this type of environment. Importantly, it is worth noting that exposure to the extreme levels of marijuana smoke in all three study sessions (i.e., non-ventilated and ventilated) does not represent a real-world situation and, therefore, is an unlikely passive exposure situation for donors in a federal agency testing program.

The marijuana studies described above indicate that transient amounts of THC may be present in nonsmokers' oral fluid between one to three hours after prolonged, extreme exposure. Conversely, however, in two similar passive exposure studies from 2001 and 2005, none of the nonsmoking subjects tested positive using cutoffs that were lower than the OFMG THC cutoffs

(i.e., 4 ng/mL for initial tests and 2 ng/mL for confirmatory tests).^{8,9} While the exposure in the 2005 study was “extreme,” both the 2001 and 2005 studies represent more likely “real world” situations than the 2015 study.

In the 2005 study of nonsmoking individuals exposed to marijuana smoke in an unventilated passenger van, none of the passively exposed individuals tested positive using a 3 ng/mL initial test cutoff when the oral fluid collection device was protected from exposure to contaminated surfaces.⁹ In this two-part study, four non-smoking subjects sat beside four active cannabis smokers who each smoked a single cannabis cigarette containing either a low dose of THC (Study 1) or high dose of THC (Study 2). In Study 1, oral fluid was collected inside the THC-contaminated van. Maximum oral fluid THC concentrations in non-smoking subjects were 7.5 ng/mL but declined to negative levels within 45 minutes of exposure. In Study 2, oral fluid was collected outside the van. Even though the dose of THC was more than twice the dose in Study 1, the maximum concentration detected in the passively exposed subjects was 1.2 ng/mL, which is well below the initial and confirmatory THC cutoffs in these Guidelines. When potential contamination during collection was eliminated in Study 2, all non-smoking subjects were negative at both initial and confirmatory cutoff concentrations throughout the study.

In the 2001 study, subjects were administered a single dose of marijuana by smoked and oral routes, and their oral fluid and urine THC test results were compared.⁸ The study used a 1 ng/mL THC initial test cutoff and a 0.5 ng/mL THC confirmatory test cutoff, both lower than the THC cutoffs in these Guidelines (i.e., 4 ng/mL initial test cutoff and 2 ng/mL confirmatory test cutoff). Two nonsmoking subjects were included to simulate passive exposure scenarios (e.g., sitting in an unventilated room where marijuana is smoked). These subjects were positive by

immunoassay using the 1 ng/mL initial test cutoff at 1- and 4-hours post-exposure but negative by the confirmatory test using a 0.5 ng/mL cutoff.

These carefully executed studies on passive exposure are considered strong evidence that exposure to secondhand marijuana smoke under normal ventilation conditions presents no risk that an individual will have a passive exposure related positive test result under the standards used in these Guidelines.

Another reason for the Department's decision to test only for THC is that THCA cannot be reliably detected in all individuals who use marijuana. Two recent studies investigated the presence of THC and THCA in oral fluid after various routes of administration.^{15,16} One study characterized marijuana analytes including THC and THCA in oral fluid of nine occasional and 11 frequent marijuana smokers after smoked, vaporized, and oral administration (i.e., ingestion of a brownie containing marijuana).¹⁵ THC was present in oral fluid specimens in all individuals from both groups, after all routes of administration, immediately after use. THC was detected above the OFMG confirmatory cutoff (i.e., 2 ng/mL) for 32 hours with the occasional users and 72 hours with the frequent users. Of the nine occasional users, all tested positive for THC using the OFMG confirmatory cutoff after all administration routes. However, only three occasional users tested positive for THCA (i.e., at or above 15 pg/mL) after all administration routes. In a second study, drug-free subjects ate brownies containing marijuana in three separate dosing sessions, with THC concentrations of 10 mg, 25 mg, and 50 mg.¹⁶ The appearance of THCA in oral fluid in this study was highly variable, and THCA was not present in all subjects. Within the first eight hours after marijuana ingestion, 116 oral fluid specimens were positive for

either THC or THCA. Of those specimens, 23 specimens were positive for both THC and THCA, 75 were positive for THC only, and 18 were positive for THCA only. Therefore, THC was detected in approximately 84.5% of the positive oral fluid tests, while THCA was only detected in approximately 35.3%. These studies support the Department's decision to test for THC by showing that THCA cannot be as reliably detected as THC in all marijuana users.

The Department's decision to use THC as the initial and confirmatory test analyte is also supported by the differences between the detection patterns of the two analytes in occasional smokers versus chronic frequent smokers. For example, one study showed that, although THCA was detected in frequent cannabis smokers almost 100% of the time studied, occasional smokers did not consistently test positive for THCA using the previously considered confirmatory test cutoff concentration of 0.05 ng/mL.¹⁷ Some individuals tested negative for THCA after smoking cannabis. Consequently, confirmatory testing for THCA without performing an initial test for THCA would be biased toward detecting chronic frequent cannabis smokers and would be ineffective in detecting occasional users. Such an outcome would diminish the reliability of marijuana testing using oral fluid. It is also important to note that occasional users may exhibit greater acute impairment than chronic frequent users due to the lack of tolerance to cannabis effects.¹⁸ This consideration suggests that an oral fluid drug testing system that relies upon testing for THCA to detect marijuana use may fail to identify occasional users who could pose a safety risk to a federal agency's enterprise.

The Department believes that an immunoassay initial test with the appropriate sensitivity for testing for both THCA and THC could allow oral fluid marijuana tests to take advantage of THCA's extended detection window. The preamble to the proposed OFMG, published on May 15, 2015, noted the lack of scientific data on the time course of excretion or the detection

window of THC, THCA, and conjugated THCA in oral fluid following marijuana use, especially for occasional users. It was noted that studies of daily marijuana smokers indicated that THC is detectable for up to two days, but THCA continued to be excreted in oral fluid during abstinence for several weeks in daily users.¹⁹ Two other studies evaluated oral fluid results following cannabis smoking (i.e., one cannabis cigarette containing 6.8% THC).^{17, 20} In a 2013 study, oral fluid was collected from 10 participants using the QuantisalTM (Immunoanalysis) oral fluid collection device over a 22-hour period.¹⁷ The authors used a 0.5 ng/mL cutoff for THC and a 7.5 pg/mL cutoff for THCA. The mean time to last concentration and the mean last concentration was 12.3 hours and 5.1 ng/mL for THC and 14.6 hours and 42.3 pg/mL for THCA, thus providing evidence of a longer detection window for THCA. A 2012 study evaluated cannabinoid concentrations in oral fluid of chronic and occasional smokers.²⁰ Oral fluid was collected 19 hours before smoking to 30 hours after smoking, using the Statsure Saliva SamplerTM (Statsure Diagnostic Systems). The authors concluded that: 1) all specimens were THC positive for up to 13.5 hours post-smoking without significant differences between chronic and occasional smokers, 2) THCA provided longer detection times than THC in the 13.5 to 30 hour post-smoking period in all chronic smokers, and 3) THCA windows of detection for chronic cannabis smokers extended beyond 30 hours.

However, the Department has not identified immunoassay technology that is feasible as an initial test for both THC and THCA in a high-throughput laboratory environment. Such technology is necessary for the implementation of THCA testing in the federal drug testing program because: 1) THCA-only testing is not a viable option for the federal drug testing program (as discussed previously), and 2) even though THCA and THC can be tested during the confirmation phase of drug testing, the theoretical advantages of THCA's longer detection

window will not be achieved unless THCA can be detected in the initial test. In other words, in the absence of a viable initial test to detect THCA, specimens positive for THCA only would not advance to confirmation testing. Therefore, until a suitable immunoassay initial test that is capable of screening for both THC and THCA is available, the Department believes that its decision to test for THC using the cutoffs established in these Guidelines provides federal agencies with an efficient, cost-effective and reliable means to detect marijuana use.

As such, it is the conclusion of the Department that a 4 ng/mL initial test cutoff for THC is supported by scientific studies and is consistent with the Department's objective of detecting the use of illicit drugs while, to the extent practicable, eliminating the risk of positive test results caused solely by the drug use of others and not caused by the drug use of the individual being tested, as directed by the SUPPORT for Patients and Communities Act, P.L. 115-271, section 8107(b).¹⁴

Lowering the initial test cutoff concentration for THC to either 2 or 3 ng/mL and lowering the confirmation test cutoff concentration for THC to 1 ng/mL to extend the window of detection for marijuana use.

Three commenters recommended lowering the THC initial test and confirmatory cutoffs to extend the window of detection; one commenter recommended lowering the initial test cutoff for this reason, but keeping the proposed confirmatory cutoff. One commenter recommended a slightly lower confirmatory cutoff (i.e., 1.5 ng/mL). Two commenters agreed with the proposed THC cutoffs.

Two other commenters recommended increasing the initial and confirmatory THC cutoffs, so claims of positive results due to passive exposure will not be justified.

The Department's decision on initial and confirmatory cutoffs is discussed above, but to reiterate, the Department concluded after careful review of all available scientific evidence that: 1) credible claims of positive THC tests resulting from second-hand smoke/passive exposure are extremely unlikely, and 2) the only scenario in which there is a theoretical possibility of testing positive for THC as the result of second-hand smoke/passive exposure under these Guidelines involves sustained exposure to extreme levels of marijuana smoke. The Department is confident that under these Guidelines, only a donor's marijuana use would be identified.

Performance requirements for an oral fluid collection device

One commenter agreed and one commenter disagreed with requiring the use of only collection devices that have been cleared by the Food and Drug Administration (FDA). One commenter suggested the requirements for collection devices should be developed by appropriate professionals after suitable scientific and stakeholder review, while another suggested the requirements be determined by laboratories and manufacturers. One commenter disagreed with the Guidelines, and suggested that only devices using "the swab technique" be required.

The Department has evaluated these comments, and maintained the requirement in Section 7.1 for oral fluid collection devices to be FDA-cleared.

Five commenters addressed proposed volume specifications. Three commenters suggested that the Department specify oral fluid collection and/or diluent volume as a percentage and not a specific volume, due to variability in commercially available devices. One commenter encouraged increasing the allowed specimen and diluent volume variance to +/- 20%. One

commenter believes that the proposed 0.05 mL diluent variance is too small and not realistic.

One commenter suggested that the Guidelines not specify a required volume, but emphasize that laboratories choose devices that would ensure sufficient volume is collected for initial and confirmatory testing. One commenter disagreed with the proposed variance in specimen collected and suggested that the device must collect a known volume (similar to the “European Guidelines for Workplace in Oral Fluid”). This commenter also disagreed with the 1 mL collection requirement, stating that LC/MS/MS methods use approximately 200 mcL of oral fluid and that reducing the volume will reduce the time required for collection.

The Department has evaluated these comments, and revised Section 7.3(b) to specify oral fluid collection and diluent volumes as percentages (rather than specific volumes as proposed). The Department agreed with commenters that specifying allowable diluent variance as a percentage rather than volume would allow different manufacturers to produce their oral fluid collection devices with an optimized volume of diluent while ensuring reliability across systems. The Department also changed the specimen volume variance to a percentage for consistency. Section 7.3 specifies variances of 2.5% for diluent volume and 10% for specimen volume, based on information obtained from device manufacturers. The Department also maintained the requirement to collect at least 1 mL of oral fluid. This is a reasonable collection volume that will enable sufficient specimen for testing (e.g., when repeat testing or confirmatory tests for multiple drugs are required).

Four commenters addressed the proposed device requirements for recovery of $\geq 90\%$ (but no more than 120%) of drug and/or drug metabolite at (or near) the initial test cutoff. The commenters disagreed with the proposed requirement of $\geq 90\%$, and suggested recovery between 80% and 120%. One commenter noted that 80% to 120% recovery is consistent with current

FDA-cleared systems. One commenter cited adherence of THC to surfaces as a problem in achieving 90% recovery, and recommended either requiring $\geq 80\%$ for all drugs or requiring $\geq 80\%$ recovery for THC and $\geq 90\%$ recovery for other drugs. One commenter agreed with specifying minimum and maximum recovery, and recommended additional emphasis on the consistency of recovery performance of the device and confirmatory methods.

The Department has evaluated these comments, and revised Section 7.3(b) to change the lower limit for drug recovery from $\geq 90\%$ to $\geq 80\%$.

Two commenters addressed stability at room temperature. One commenter agreed with the requirement for stability at room temperature for at least one week, and one commenter disagreed. This commenter indicated that in-house studies found cocaine and 6-AM were unstable for that length of time and also indicated that specimens are typically received at the laboratory one to two days after collection.

The Department has evaluated these comments, and changed the stability requirement in Section 7.3(b) from one week at room temperature to five days at room temperature. Because oral fluid is collected with either a preservative buffer (i.e., collection device with diluent) or preservative dry reagents (i.e., neat oral fluid collection), normal transport conditions are not expected to affect stability of the drugs and/or drug metabolites. The Department will include guidance to collectors concerning proper collection and transport of oral fluid specimens in the Oral Fluid Specimen Collection Handbook.

Medical Review Officer (MRO) reporting procedures for positive morphine/codeine results

In Section 13.5, the Department proposed a concentration of 150 ng/mL for codeine and morphine to be used by the MRO to report a positive result in the absence of a legitimate medical

explanation (i.e., prescription), without requiring clinical evidence of illegal use, and to rule out the possibility of a positive result due to consumption of food products. The Department requested comments on the appropriateness of this concentration. One commenter agreed. Six commenters disagreed: one commenter recommended 100-120 ng/mL, one commenter recommended 50-100 ng/mL, one commenter recommended 120 ng/mL, and one commenter recommended 40 ng/mL. One commenter suggested that no additional decision point is needed because, based on scientific studies including in-house studies, positive opiate results using a 40 ng/mL cutoff are not typical and are difficult to achieve, thus there is no justification for an MRO reversal of a codeine or morphine result less than 150 ng/mL. One commenter expressed concern that the 150 ng/mL decision point would not rule out positive codeine/morphine results due to food products and suggested that the Department use a much higher decision point or require clinical evidence of illegal drug use before an MRO verifies any opiate results as positive. Based on evaluation of these comments and examination of the data from scientific studies, the Department has concluded that no change is needed.²¹⁻²⁴ The 150 ng/mL concentration is higher than the highest concentration seen in study subjects at one hour and later after consumption of raw poppy seeds and products containing poppy seeds.

HHS list of FDA-cleared oral fluid collection devices

The Department requested comments on whether HHS should publish a list of FDA-cleared oral fluid collection devices. Seven commenters agreed. One commenter disagreed, stating that it is sufficient to provide regulation on requirements and noting that the Department does not publish a list of FDA-cleared urine specimen containers. After further review, the Department has decided not to publish a list. The list might not reflect all current FDA-cleared oral fluid

collection devices, and could be misconstrued as a list of SAMHSA-approved devices. Also, FDA clearance does not mean that the collection device meets OFMG requirements. The federal agency and/or the HHS-certified laboratory must ensure that the FDA-cleared device meets the device requirements in Sections 7.2 and 7.3. FDA has a searchable database on its website that can be used to identify FDA-cleared oral fluid collection devices. The Department will include a link to this database on the SAMHSA website <http://www.samhsa.gov/workplace>.

Medical Review Officer (MRO) requalification - continuing education units (CEUs)

The Department requested comments on requiring MRO requalification continuing education units (CEUs) and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification. Three commenters agreed with requiring MRO recertification, but disagreed with the addition of CEU requirements to the Guidelines. Two commenters disagreed with specifying the number of CEUs required. Two commenters indicated that certification entities already enforce training requirements and recommended that acceptance of CEUs be handled by MRO certification boards, not the Department. Two commenters recommended a requirement of annual CEUs: one suggested 16 CEUs and the other recommended three CEUs. One commenter recommended 12 CEUs prior to initial certification, eight CEUs every five years, and also recommended two CEUs related to the new requirements/topics within two years of implementation of the revised Guidelines. The Department has evaluated the comments and has concluded that requirements for continuing education units will remain with the MRO certification entities and will not be included in the Guidelines. The Department has removed references to MRO training entities in Sections 13.2 and 13.3, because training documentation is maintained by MRO certification entities. The

Department agrees with the comment that MROs should receive training on revisions to the Guidelines and has added item Section 13.3(b) to require such training prior to the effective date of revised Guidelines, to ensure that all MROs are trained in program requirements before performing MRO duties for federal agency specimens.

Split specimen collection methods

All federal agency collections are to be split specimen collections. The donor's primary (A) specimen is tested and the split (B) specimen is available for testing if the donor requests a retest at another HHS-certified laboratory. For urine, one specimen is collected from the donor, then the collector pours the collected specimen into two bottles that are then labelled as A and B specimens. Most current oral fluid collection devices collect a single specimen that cannot be divided into A and B specimens. Therefore, the Department requested comments on whether serial or simultaneous collection using two collection devices constitutes a split oral fluid collection, and recommendations for any other oral fluid collection processes that enable subdividing the collected specimen. Three commenters agreed with the proposed guidelines as written. Two cited problems with collecting expectorated oral fluid (i.e., difficult to obtain a sufficient specimen, distasteful to donor and collector), and stated that collection with a device provides analyte stability, a homogenous specimen, and facilitates processing in the laboratory. The commenters noted that the split specimen requirement to identify the presence of the drug addresses any concentration differences between first and second specimens. They also noted that split collections with two devices are currently used for non-regulated testing without issue and that scientific studies support these methods. Five commenters disagreed. Some raised concerns over possible insufficient specimen volume and non-homogenous specimens leading to

possible discrepant primary and split specimen results. One commenter disagreed stating that the use of two devices for each collection increases costs. One commenter believes that serial collections using two devices may increase the likelihood of collection problems (e.g., collector forgets to perform the second collection; the donor may leave the collection site or be out of collector's line-of-sight between collections; the two-minute period may be exceeded). The Department has evaluated the comments and has concluded that no change is needed. Either serial or simultaneous collection using two collection devices constitutes a split oral fluid collection for federal workplace drug testing programs. These split collection procedures are described in Section 8.8. The Department revised the split specimen collection definition in Section 1.5 and revised Section 8.8(a) to clarify that the OFMG do not prohibit collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. In Section 2.5, the Department clarified that the split oral fluid specimen may be collected using two devices or using one device and subdividing the specimen.

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or where minor typographical or grammatical changes were made.

Subpart A – Applicability

1.5 What do the terms used in these Guidelines mean?

One commenter requested that “external service provider” be defined, because this is a new term included in the proposed Guidelines. The Department agrees and has added the definition “An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).”

Two commenters disagreed with the proposed definition for “invalid result” which indicated that an invalid result was reported only when an HHS-certified laboratory could not complete testing or obtain a valid drug test result. The Department agrees and has reinstituted wording from the definition in the Guidelines effective October 1, 2010 (73 FR 71858). The definition in Section 1.5 is “The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.7 when a positive or negative result cannot be established for a specific drug or specimen validity test.”

To address comments described in this preamble under Section 13.1, the Department deleted the definition for “non-medical use of a drug.”

Two commenters found the definition of “specimen” confusing, because the term “sample” used in the definition was also defined as a representative portion of a donor’s specimen. The Department agrees and has reinstituted some wording for the definition of “specimen” from the Guidelines effective October 1, 2010 (73 FR 71858) for clarity. The definition in Section 1.5 is “Fluid or material collected from a donor at the collection site for the purpose of a drug test.”

The Department revised the definition of “split specimen collection (for oral fluid)” to clarify that the OFMG allow collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. This is consistent with the change described in this preamble under Section 8.8(a).

For clarity, the Department added a definition for the term “undiluted (neat) oral fluid” which is used throughout the OFMG. The definition in Section 1.5 is “An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.”

1.6 What is an agency required to do to protect employee records?

One commenter suggested that the non-applicability of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) should be clearly stated in the Guidelines. The Department has evaluated the comment and has concluded that the applicability of HIPAA and other relevant privacy laws is clearly stated in Section 1.6. Accordingly, except for minor rewording for clarity, no further revisions are necessary.

1.7 What is a refusal to take a federally regulated drug test?

The Department proposed within Section 1.7 what is a refusal to take a federally regulated drug test. Two commenters noted that this section does not include the same requirements as Section 1.7(a)(10) of the UrMG defining a refusal to test when a collector finds a device intended for the purpose of adulteration or substitution and recommended adding similar language to the OFMG. The Department has evaluated the comments, and agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor’s clear attempt to tamper with a specimen. The Department has revised Sections 1.7, 8.3(d), and 8.4(c)

accordingly. Collectors will inspect the donor's oral cavity to ensure it is free of items that may impede or interfere with the drug test as described in Section 8.3.

One commenter recommended that OFMG Section 1.7 include the same requirements as UrMG Section 1.7(a)(5) defining a refusal to test when the donor failed to provide a sufficient amount of specimen when directed, "and the required medical evaluation did not identify a legitimate medical explanation for the failure." The Department agrees with this comment and has added a new item 4 to Section 1.7(a) consistent with the UrMG requirement.

One commenter recommended clarification that a donor's refusal to provide a split specimen will also qualify as a refusal to test. The Department has evaluated the comment and has added this as a refusal to test in Sections 1.7(a)(7) and Section 8.5(b). If the donor refuses to provide a split specimen, the collector will report this as a refusal to test.

Also in regard to Section 1.7, one commenter suggested expanding the section to include specific actions that would be classified as a refusal to test. The commenter suggested wording under the current example "disrupt the collection process" describing actions specific to OF collections "(e.g., disrupt the collection process including: biting on the collection device, sucking the fluid back out of the device, failure to open mouth when directed for inspection, failure to rinse mouth when directed, failure to remove foreign object from mouth when instructed, failure to permit the observation or monitoring of the specimen collection, avoiding swabbing in-between teeth and the gum line when instructed, failure to follow the collector's instructions on swab location in the mouth, attempting to conceal chemicals or mints in the mouth, attempting to use a mouth wash immediately prior to or during the collection, attempting to chew ice during the collection, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, possess or wear a

prosthetic or other device that could be used to interfere with the collection process, other failures to comply with the collector's instructions or attempt to defraud the drug test)".

The Department has evaluated the comment and has added the failure to rinse the mouth when directed by the collector as an example of donor actions classified as a refusal to test in Sections 1.7(a)(7) and in Section 8.3(d)(2). It should be noted that Section 1.7(a)(7) lists some examples. In practice, the trained collector determines whether the donor's action is a refusal to test. Many of the commenter's described actions would disrupt the collection process and thus constitute a refusal to test under Section 1.7(a)(7). The Department will consider the commenter's suggestions during preparation of guidance which will be provided in the HHS Oral Fluid Specimen Collection Handbook.

One commenter noted that the collector does not report a refusal to test when a donor leaves the collection site before the collection process begins for a pre-employment test. The commenter recommended defining the beginning of the pre-employment collection process as the point at which the donor is asked to present photo identification. The Department agrees with the suggestion to define the beginning of the collection process specifically for this situation. However, the Department has designated the beginning as the step described in Section 8.4(a), when the collector provides or the donor selects a specimen collection device. The Department has revised Sections 1.7(a)(2) and (3) to include a reference to this section. All subsequent items in Section 1.7(a) (i.e., items 4 – 10) apply once the donor has arrived for the pre-employment test collection.

1.8 What are the potential consequences for refusing to take a federally regulated drug test?

The Department reworded Section 1.8(b) to clarify that the requirements in this section apply to donors who fail to appear at the collection site in a reasonable time for any test (except a pre-employment test), as described in Section 1.7(a)(1).

Subpart B – Oral Fluid Specimens

2.1 What type of specimen may be collected?

Ten commenters agreed with adding oral fluid and three commenters disagreed with adding oral fluid and alternate matrices. One commenter raised questions regarding the accuracy of oral fluid testing, MRO interpretation of detection of the parent compound of a prohibited drug, and the cost of oral fluid testing. The Department has evaluated the comments, and believes the concerns raised by the commenters are not sufficient to remove oral fluid testing from the Guidelines. The Department believes that collecting and testing oral fluid specimens according to the requirements in these Guidelines is an efficient means to detect illicit drug use and ensures that the oral fluid test results are forensically and scientifically supportable.

Numerous commenters expressed concern with the Department's urine collection policy, stating that 7 to 10% of Americans have a condition ("paruresis"), described as a social anxiety disorder which prevents a person from producing urine on demand or in the presence of other people. These commenters stated that if the government wants to seek the largest group of qualified applicants, the Guidelines should specify that a diagnosis of paruresis means non-urine (i.e., oral fluid) testing will automatically be provided, and that donors should not have to attempt to provide a urine specimen first. These comments are not relevant to the OFMG. The OFMG establish the standards and technical requirements for oral fluid testing in federal

workplace drug testing programs. Each federal agency will decide whether to collect urine, oral fluid, or both specimen types in their workplace testing programs.

2.2 Under what circumstances may an oral fluid specimen be collected?

One commenter recommended that oral fluid be restricted based on the reason for the test due to the short window of detection compared to urine (and hair), the benefits of observed collection, and the ability to identify the parent or active drug that was used. One commenter recognized the benefit of oral fluid with respect to fewer adulterated, substituted, and/or invalid specimens, but raised concern over the shorter window of detection in oral fluid, especially with respect to pre-employment testing. Two commenters suggested that oral fluid and hair testing be performed for pre-employment and random tests. The Department has evaluated the comments and has concluded that no change is needed. Each federal agency will decide which of the authorized specimen types it will collect and the reasons for collecting each type of specimen.

2.3 How is each oral fluid specimen collected?

One commenter noted that this section does not clearly describe a split specimen “collected either simultaneously or serially.” The Department has evaluated the comment and has revised this section to include a reference to Section 8.8, which provides clear descriptions of these split specimen collection methods.

2.4 What volume of oral fluid is collected?

2.5 How is the split oral fluid specimen collected?

Comments on these two sections (i.e., Section 2.4 and Section 2.5) are addressed here. One commenter noted that Sections 2.4 and 2.5 require collection of “a known volume” of at least 1 mL undiluted oral fluid, and stated that an absorbent pad device will not meet this requirement. The commenter recommended that these sections be clarified and address all types of oral fluid collection devices. The Department has evaluated the comment and has revised Sections 2.4 and 2.5 to ensure consistent requirements for collection devices with and without a diluent (or other component, process, or method that modifies the volume of the testable specimen). The Department revised Section 2.4 to require A and B tubes to have a volume marking clearly noting a level of 1 mL if the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen). This is consistent with requirements in Section 7.3 for devices that modify the volume of the testable specimen to have a volume indicator, to ensure that at least 1 mL of oral fluid is collected. In Section 2.5, in addition to referencing Section 8.8, the Department clarified that the split oral fluid specimen may be collected using two devices or using one device and subdividing the specimen.

Subpart C- Oral Fluid Specimen Tests

3.1 Which tests are conducted on an oral fluid specimen?

One commenter suggested changing the term “opiates” to “opioids” in the Guidelines. “Opiates” is the term used to describe naturally occurring substances known as alkaloids derived from the opium poppy plant (e.g., codeine; morphine; and heroin, which is produced by the acetylation of morphine) that bind to specific receptors in the central nervous system. The broadly used term “opioids” includes opiates (e.g., codeine, morphine, and heroin); semi-

synthetic compounds (e.g., hydrocodone, hydromorphone, methadone, oxycodone, and oxymorphone); and synthetic compounds (e.g., fentanyl). The Department agrees with the commenter and has changed the term “opiates” to “opioids” where appropriate to refer to oxycodone, oxymorphone, hydrocodone, and hydromorphone in addition to codeine, morphine, and 6-acetylmorphine (6-AM).

In addition, as described under *Requirements for specimen validity testing* in this preamble, the Department revised Section 3.1 to allow, but not require, oral fluid specimen validity testing.

3.2 May a specimen be tested for additional drugs?

The Department reworded Section 3.2(a) to clarify the additional drug tests that may be performed on federal employee specimens.

3.3 May any of the specimens be used for other purposes?

It should be noted that, consistent with the Urine Mandatory Guidelines, Section 3.3 specifically prohibits conducting, among other types of testing, deoxyribonucleic acid (DNA) testing, on oral fluid specimens unless authorized in accordance with applicable federal law.

3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?

Comments concerning marijuana test cutoffs are addressed under the *Testing for Marijuana* Use section above. Comments on other drug test cutoffs are addressed under *Proposed cutoff concentrations*. To summarize, the Department revised Section 3.4 to use higher cutoffs for some drugs (i.e., initial test cutoffs for 6-AM, PCP, and amphetamines; confirmatory test cutoffs

for PCP and amphetamines) than in the proposed OFMG. Other comments related to Section 3.4 are addressed below.

Three commenters disagreed with testing for cocaine in oral fluid, stating that cocaine is not stable in oral fluid, especially at the pH of human oral fluid. The commenters noted that cocaine has a short half-life and hydrolyzes to benzoylecgonine, and that benzoylecgonine is present longer and at higher levels. Two of these commenters further noted that the current industry standard is to test for benzoylecgonine only in oral fluid. One stated that their in-house studies found that testing cocaine did not increase the positivity rate compared to testing only benzoylecgonine. The other commenter refuted the study cited in the preamble to the proposed OFMG that supported the inclusion of cocaine as a test analyte. The Department based the proposed analytes for each drug on the recommendations of a technical workgroup consisting of subject matter experts and representatives from various stakeholder groups (e.g., collection device and test kit manufacturers, oral fluid drug testing laboratories). In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, page 28063), the Department included the scientific basis for including both analytes. The inclusion of both cocaine and benzoylecgonine as test analytes will increase the number of specimens that are identified as containing these cocaine analytes and, thereby, will increase the deterrent effect of the program and improve identification of employees using this drug.

One commenter disagreed with testing for hydromorphone and oxycodone in oral fluid due to extremely low incidence and recommended testing for more prevalent metabolites. The Department has evaluated the comment and decided that no change is needed. Information provided by initial test manufacturers indicates that the proposed analytes (i.e., parent drugs) are present in higher concentrations and in the absence of their metabolites.

One commenter recommended specifying D-isomers as the initial test analytes for amphetamines. The Department agrees that an antibody that is directed toward D-enantiomers in an immunoassay method should be preferred over an antibody that is non-stereoselective, but concluded that no change is needed. The wording in this section is consistent with the UrMG, and the selection of an immunoassay kit or methodology will remain the testing laboratory's choice.

An HHS-certified laboratory may group analytes for initial testing. For clarity, the Department has defined the term “grouped analytes” where used in footnote 1 of the table in Section 3.4: “(i.e., two or more analytes that are in the same drug class and have the same initial test cutoff).”

The Department proposed criteria for calibrating initial tests for grouped analytes such as opioids and amphetamines, specifying the minimum cross-reactivity to the other analyte(s) within the group. The Department also proposed including methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes. Four commenters stated that 80% cross-reactivity may not be possible with current immunoassay technology, so may require independent analyses (e.g., hydrocodone and hydromorphone for an opiate assay; MDEA for an amphetamines assay). Two of these commenters noted concerns with additional oral fluid specimen volume needed for the independent assays. Another commenter stated that cross-reactivity specifications for hydromorphone are not necessary, based on their non-regulated testing results (i.e., confirmatory test concentrations detected after using an immunoassay with 60% cross-reactivity for hydromorphone).

The Department has evaluated these comments and concluded that no change is needed for immunoassay cross-reactivity requirements. The cross-reactivity requirements in Section 3.4 are

necessary to ensure consistency in testing among laboratories using different immunoassay kits, as well as those using different test methods for initial drug testing. Cross-reactivity must be demonstrated and documented by the manufacturer (e.g., package insert) and by the HHS-certified laboratory (i.e., assay validation studies, reagent lot verification, and batch quality control for any analyte that exhibits less than 100% cross-reactivity).

One commenter stated that the low prevalence of MDA and MDEA does not warrant the burden placed on immunoassay manufacturers and laboratories. The Department has evaluated the comment and has removed MDEA from the Guidelines (i.e., MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified urine laboratories (i.e., information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs. Because MDEA is a Schedule I drug, a federal agency may test specimens for MDEA in accordance with Section 3.2 (i.e., on a case-by-case basis for reasonable suspicion or post-accident testing, routinely with a waiver from the Secretary). The Department understands that some other analytes have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Also in Section 3.4, the Department did not specify the target analyte to be used to calibrate an initial test for grouped analytes such as amphetamines or opioids. Three commenters noted that when an immunoassay is calibrated with a low-reacting drug, other analytes may exhibit high cross-reactivity, leading to false initial test positives. Two of these commenters also noted that this may result in possibly different cross-reactivity profiles for some structurally unrelated

and concomitantly used prescription and/or over the counter drugs. It was not the Department's intent for the laboratory to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. In the preamble to the proposed OFMG, the Department described using a control containing the lowest reacting analyte at its cutoff concentration to establish the decision point (i.e., when an immunoassay for grouped analytes did not demonstrate at least 80% cross-reactivity to each analyte). The Department has determined that this approach is not necessary, and will not be permitted. There are current immunoassays that meet the requirements of this section for two or more analytes in a group (i.e., analytes in the same drug class that have the same initial test cutoff). As indicated in Section 3.4, the laboratory may use multiple test kits or a single kit to meet the requirements.

However, the Department has revised Section 3.4 regarding the use of alternate technology initial tests for THC and 6-AM. To ensure consistent treatment of specimens, depending on the technology, the confirmatory test cutoff (i.e., 2 ng/mL) must be used for THC and 6-AM. For example, because immunoassays cross-react with various marijuana constituents and metabolites, a specimen that is positive using a cutoff of 4 ng/mL for an immunoassay may not test positive using an alternate technology initial test with a 4 ng/mL cutoff for THC. When using an alternate technology initial test (e.g., LC/MS/MS) that is specific for the target analyte, THC, must be tested using the confirmatory test cutoff.

3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

One commenter recommended that HHS maintain a list of allowable additional tests and reporting criteria (e.g., threshold for reporting as positive, adulterated, substituted, and/or invalid,

and a limit of detection as appropriate), to ensure consistency among laboratories and within the testing program. The Department has evaluated the comment and has concluded that no change is needed. The Department does not want to limit the analytes that may be tested, and will provide guidance to laboratories as necessary. It is also noted that the section requires all tests to meet appropriate validation and quality control requirements. The procedures and specimen records for such tests will be reviewed at NLCP inspections. The Department will continue to maintain a list of HHS-certified laboratories that choose to perform additional tests for regulated specimens. The Department has reworded Section 3.5 in concert with revisions to Section 3.1 removing the requirement for albumin or IgG testing, as described under *Requirements for specimen validity testing* in this preamble.

One commenter asked whether an MRO could submit a blanket request to perform additional testing (e.g., additional opioid metabolites) for all confirmatory specimens (i.e., would laboratories be permitted to monitor the additional compounds in all confirmatory test assays?). The Department believes that testing all specimens for additional analytes may not be appropriate for some tests, especially hydrocodone, hydromorphone, oxycodone and oxymorphone. Recent studies show that testing for norhydrocodone and/or noroxycodone is not necessary for the interpretation of all results.^{26,27} Norhydrocodone and noroxycodone metabolites may be helpful for the MRO to interpret test results only when a donor's prescription does not support the test results. The presence of norhydrocodone metabolite would support the use of hydrocodone and validate the donor's prescription. The same could be said for interpreting test results following an oxycodone dose. The presence of noroxycodone metabolite would support the use of oxycodone and validate the donor's prescription. The Department will provide guidance on these and other additional tests that may provide useful information for the

MRO in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department has revised Section 3.5 to clarify that HHS-certified laboratories are authorized to perform additional tests upon MRO request on a case-by-case basis, but are not authorized to routinely perform such tests without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. The Department will continue to allow HHS-certified laboratories to test for D,L amphetamine and methamphetamine routinely or upon MRO request. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO (e.g., tetrahydrocannabinavarin) in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

Additional drug and specimen validity testing under Section 3.5 does not include DNA testing.

3.7 What criteria are used to report an invalid result for an oral fluid specimen?

One commenter disagreed and recommended deleting Sections 3.7(a-c) and 3.7(g) from the Guidelines due to observed collections by trained collectors. As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 3.7 has been revised accordingly.

Subpart D – Collectors

4.1 Who may collect a specimen?

One commenter questioned why the Department prohibits supervisors or hiring officials from collecting oral fluid specimens (unless no other collector is available). The commenter cited fewer privacy concerns in collecting oral fluid versus urine, and indicated that having supervisors collect specimens would be particularly useful in remote locations and/or for post-accident tests. The Department has evaluated the comments and has concluded that no change is needed. The Department will continue to prohibit routine collections by a supervisor, to avoid potential conflicts of interest due to the employee-supervisor relationship as much as possible. The Guidelines permit collections by a supervisor who has been trained as a collector when no other trained collector is available.

4.2 Who may not collect a specimen?

One commenter expressed concern that this section as written may unintentionally prevent the use of valid collection methods (i.e., preventing the donor from collecting their own specimen may prohibit the donor from holding the collection device). The Department has evaluated the comments and has concluded that no change is needed to Section 4.2, which includes general language concerning the entire collection process. Section 8.4 describes steps the collector takes before the donor provides the oral fluid specimen, including reviewing with the donor the manufacturer's instructions for oral fluid collection using the specimen collection device. Section 8.5 describes the collection procedure, including the requirement for the donor to position the device for collection, and for the collector and donor to complete the collection in accordance with the manufacturer's instructions for the collection device. However, the Department has revised the wording in Section 8.5(a)(1) to address all types of oral fluid collection devices allowed by the OFMG (i.e., including those that are not placed in the mouth).

Subpart E - Collection Sites

5.2 What are the requirements for a collection site?

One commenter suggested that the Department require restricted access only to be applicable during a collection period, and allow supplies and records to be stored in nearby secured areas. The Department has evaluated the comments and has concluded that no change is needed. The section clearly describes the requirements and addresses the commenter's concerns.

Subpart F - Federal Drug Testing Custody and Control Form (CCF)

6.1 What federal form is used to document custody and control?

6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

Comments on these two sections (Sections 6.1 and 6.2) are addressed here. Three commenters recommended that the Federal Custody and Control Form (CCF) be revised to address oral fluid specimens. The Department will revise the Federal CCF when Guidelines allowing oral fluid become effective.

The Department reworded items 6.2(b) and (c) for clarity.

Subpart G – Oral Fluid Specimen Collection Devices

7.3 What are the minimum performance requirements for a collection device?

The Department reworded Section 7.3(a) in reference to oral fluid collection volume, as described under Sections 2.4 and 2.5 above, and revised Section 7.3(b) in response to public comments, as described under *Performance requirements for an oral fluid collection device* above.

Subpart H – Oral Fluid Specimen Collection Procedure

8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

One commenter stated that this section requires the collector to deter adulteration or substitution at the collection site, but does not provide any information on how this is to be done. The commenter recommended that Section 8.2 be deleted or, alternatively, that additional information be added to the section. The Department has evaluated the comments and has concluded that no change is needed. The section provides the general requirement; the Department will provide more specific guidance as needed in the HHS Oral Fluid Specimen Collection Handbook, which will be issued after these Guidelines become effective.

8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

In response to comments described under Sections 1.7 and 8.4 in this preamble, the Department revised Section 8.3(d) to require the collector to report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site.

One commenter requested that the Guidelines clarify (possibly using a flowchart) the different waiting periods in Sections 8.3 and 8.6 (i.e., if multiple waiting periods are required, do

they run concurrently or consecutively?). The Department has evaluated the comments and has concluded that no change is needed. The Department will consider the commenter's suggestion during preparation of the HHS Oral Fluid Specimen Collection Handbook.

Several comments concerned Section 8.3 collection procedures regarding rinsing or drinking. One commenter disagreed with the requirement to have tobacco users rinse their mouth prior to an oral fluid collection, noting it is an inconvenience for the collector to provide a place for the donor to spit out the liquid. One commenter requested clarification on oral fluid collection procedures for tobacco users (e.g., is the collector required to ask, is it a refusal if a tobacco user doesn't rinse their mouth, is the donor required to rinse with water, what if the donor uses more than 4 oz. of liquid to rinse?). The Department removed the reference to tobacco users in 8.3(d)(2) because there is no need for all tobacco users to rinse their mouths. The proposed procedure for tobacco users was due to the dark brown color of tobacco juice. The issue is that any discoloration may interfere with initial testing (i.e., not just tobacco juice). The Department reworded this section to include abnormally colored saliva as a reason for the collector to give water to the donor for rinsing their mouth.

One commenter recommended that the Guidelines clarify that if the donor drinks water, the water must not be provided by the donor. For clarity, the Department revised Section 8.3(d)(2) to require the collector to give the donor water (for example, up to 4 oz.) to rinse the donor's mouth when the collector's inspection of the oral cavity identifies any items that could impede or interfere with the collection of an oral fluid specimen. If the donor refuses to rinse, this is a refusal to test. Rinsing with more than 4 oz. of water does not invalidate the collection, so this amount was given as an example rather than a requirement.

One commenter indicated that some collection devices specifically instruct against offering the donor anything to rinse with or drink. This commenter suggested modifying Section 8.3 to make offering of water conditionally allowed, depending on the collection device manufacturer's instructions. The Department has evaluated these comments and concluded that no change is needed. The Department believes that rinsing the oral cavity with water prior to a 10-minute wait period is a reasonable part of the oral fluid collection protocol. The wait period is sufficient to comply with the device instructions, and will not dilute the collected oral fluid.

Several comments concerned Section 8.3 collection procedures regarding inspection of the donor's mouth. One commenter requested clarification on what items need to be removed from a donor's mouth prior to an oral fluid collection (tobacco, food, gum, or mints versus retainers and piercings). One commenter requested clarification of whether "dental retainer" refers to a temporary or permanent device (or both), should the device be removed and, if so, where the device should be placed during the oral fluid collection. The Department has evaluated the comments and concluded that only one change is needed: removal of "dental retainer" from the examples of items that must be removed based on a collector's inspection of the donor's mouth in Section 8.3(d). A donor is not required to remove dental appliances such as a retainer. The Department will provide additional information in the Oral Fluid Specimen Collection Handbook to clarify items that may impede or interfere with the collection.

One commenter recommended that the Guidelines address the situation where a donor may have a medical condition that prevents them from opening their mouth for the collector to inspect. The Department agrees with the commenter and has revised Section 8.3(d) to address this situation. The collector will proceed with the same steps as when a donor is unable to

provide an oral fluid specimen, as described in Section 8.6(b)(2), and the MRO will follow the steps in Section 13.6(b) requiring a medical evaluation of the donor.

8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

Two commenters believe that if the collector finds an adulterant or substitution product, this should be a refusal to test. As noted under Sections 1.7 and 8.3 in this preamble, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.4(c) accordingly.

The Department deleted Section 8.4(b)(1) for consistency with Section 8.6(b). The deleted item stated that the collector may set "a reasonable time for a collection based on the device used, not to exceed 15 minutes." Section 8.6(b) states that the donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

One commenter suggested that the section should state that the collector be present and maintain visual contact with the donor and collection device during the procedures outlined in this section. The Department has evaluated the comment and has concluded that no change is

needed: Sections 8.4(a) and 8.5(a) clearly require the collector to keep the unwrapped collection devices and the donor in view at all times during the collection.

One commenter asked if there was a limit to the number of times a collection could be restarted due to collection device failures. The Department has evaluated the comment and has reworded Section 8.5 for clarity. Section 8.5(a)(1) was revised to indicate that a failure to provide a specimen (which may or may not be due to device failure) prompts recollection using a new device and that the collector documents the failed collection attempt on the Federal CCF. The Department also reworded Section 8.5(b) to clarify that a donor's refusal to begin the collection process after a failure to collect the specimen is a refusal to test. The Department did not set a limit for the number of attempts because there may be different reasons for failing to collect the specimen from the donor. However, the Department revised the section to require the collector to follow the procedure in Section 8.6 "after multiple attempts to collect the specimen."

One commenter stated that HHS should clarify that a donor's refusal to provide a split specimen will also qualify as a refusal to test. The Department agrees with the comment and has revised Section 8.5(b) to include the refusal to provide a split oral fluid specimen as a refusal to test.

Additionally, as described under Section 4.2 above, the Department revised Section 8.5(a)(1) to address all types of collection devices allowed by the OFMG (including those that are not placed in the mouth).

8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

Three commenters disagreed with the requirement for the collector to contact the agency representative for authorization to collect an alternate specimen each time a donor is unable to provide a sufficient volume. These commenters suggested that the Guidelines allow this to be addressed in established standard protocols for the agency. The Department agrees with the commenters. Each federal agency may decide whether to require notification in each case or whether to provide a standard protocol for collectors to follow. Section 8.6 has been revised accordingly.

Also in regard to Section 8.6, one commenter requested additional information on donor hydration during an oral fluid specimen collection (i.e., asking if there is evidence that hydration improves the ability to provide a specimen and whether hydration dilutes the specimen). One commenter indicated that the volume of oral fluid collected does not appear to be directly related to fluid intake and suggested that, because some donors may not be able to provide a sufficient specimen even after the one hour wait time, a urine specimen should be collected immediately. One commenter disagreed with the one hour period allowed for an oral fluid collection, and indicated that there is no evidence provided that dry mouth is eliminated by waiting one hour. The commenter indicated that this extra time allotted costs the employer unnecessary time and money, and maintained that a waiting period of 10 minutes after consumption of 8 oz. of water is sufficient. The Department has evaluated the comments and concluded that no change is needed to Section 8.6. The proposed procedure sets a reasonable time limit within which most donors would be able to provide an acceptable specimen volume (i.e., 10 minutes between attempts to provide the oral fluid specimen, up to one hour), and the section clearly states that the donor is not required to drink any fluids during the wait time. The Guidelines clearly describe the limited circumstances in which the collector offers the donor fluids. However, the Department has

revised Section 8.8(a)(2) to expressly prohibit rinsing or drinking between the collection of the primary and split specimens when serially collected.

8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

One commenter disagreed with the Guidelines as written and suggested that when a donor cannot provide the primary specimen type, an alternate specimen should be collected immediately. The commenter cited the additional time and cost as well as the fact that the collector may not know the agency's policy on alternate specimen types. The Department has concluded that no change is needed for Section 8.7 in response to this comment. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide an oral fluid specimen as described in Sections 8.5 and 8.6. The Department has revised Section 8.6 to allow a federal agency to either require notification in each case or provide a standard protocol for collectors to follow when the donor is unable to provide an oral fluid specimen. The Department has reworded this section to state "Yes, if..." rather than "No, unless..." in response to a federal agency's comment and to enhance clarity. The meaning of this section remains the same.

8.8 How does the collector prepare the oral fluid specimens?

One commenter requested clarification of the "simultaneous" oral fluid collections. The Department has evaluated the comment and has concluded that no change is needed. Section 8.8(a)(1) describes "Two specimens collected simultaneously with two separate collection devices."

One commenter expressed concern that the requirement for a serial collection of a split specimen to begin within two minutes of the first collection may be difficult to monitor and may lead to differences between the two specimens. This commenter requested clarification on how this process will be monitored. One commenter agreed with the two-minute maximum time between serial collections of a split specimen. The Department has evaluated the comments and agrees with the second commenter that no change is needed. The proposed procedure in Section 8.8 sets a reasonable time within which the collector can take the first collection device from the donor and record the time on the Federal CCF, while the donor positions the second device for the collection. Because the collector works with one donor at a time, the collector should have no difficulty monitoring the time between primary and split collections. Furthermore, the Department believes this timing would not affect results of the primary and split oral fluid specimens.

One commenter disagreed with the proposed two-minute maximum time between serial collections of a split specimen and suggested that the time be increased to 10 minutes (so as not to rush the collector in completing chain of custody forms). This commenter suggested that a second specimen should only be collected after an initial test result is obtained (which the commenter indicates can usually be done in 10 minutes). The Department has evaluated the comments and has concluded that no change is needed. The collector is not required to complete the Federal CCF until both the primary and split specimens have been collected. Point of collection testing is not allowed under these Guidelines. That is, all testing must be performed at an HHS-certified test facility.

One commenter asked whether hydration would be allowed between serial split collections. The Department revised Section 8.8(a)(2) to expressly prohibit rinsing or drinking between the

collection of the primary and split specimens when serially collected. Prohibiting rinsing or drinking will better ensure consistency of the primary and split specimens.

The Department added an additional item under Section 8.8(a) to clarify that the OFMG allow collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. A similar change was made to the definition of “split specimen collection (for oral fluid)” in Section 1.5.

The Department also removed the word “known” in Section 8.8(b) in reference to oral fluid collection volume, as described under Sections 2.4 and 2.5 above.

In response to a federal agency comment, the Department deleted a sentence in item 8.8(h) that required the collector to send a copy of the Federal CCF to the HHS-certified laboratory. The Department agreed with the federal agency that this instruction is redundant because item 8.8(g) instructs the collector to distribute copies of the Federal CCF as required.

Subpart I – HHS-Certification of Laboratories

9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

One commenter noted that, because proposed initial test requirements allow calibration with a low-reacting analyte, PT schemes would likely need to be designed based on the specific implementation at each laboratory. The commenter provided an example: when an immunoassay is calibrated with a drug/metabolite that exhibits 50% cross-reactivity, the intended target analyte (“calibrant”) at the cutoff concentration would elicit a response well in excess of the cutoff. This could result in inaccurate initial test results (i.e., a positive initial test result for a

specimen containing the calibrant at a concentration below the cutoff). The commenter stated that this result could be scored as a “false positive” PT result. The Department has evaluated the comment and has concluded that no change is needed. As noted above regarding Section 3.4, it was not the Department’s intent for the laboratory to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. NLCP PT schemes are designed based on known cross-reactivity profiles of the initial tests used by HHS-certified laboratories.

Also in regard to proposed Section 9.5, one commenter suggested that the Guidelines use the same wording as in the Guidelines effective October 1, 2010 (73 FR 71858) for retest PT sample specifications (i.e., “...may be as low as...” rather than the proposed wording “...may be less than...”). The Department agrees and has reinstituted wording from Section 9.3 of the Guidelines effective October 1, 2010 (73 FR 71858) into Section 9.5(a)(1)(ii).

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 9.5 has been revised accordingly.

9.6 What are the PT requirements for an applicant laboratory?

9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

Comments on these two sections (Sections 9.6 and 9.7) are addressed here. As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Sections 9.6 and 9.7 have been revised accordingly.

Subpart J - Blind Samples Submitted by an Agency

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

Two commenters disagreed with the proposed limit to the number of blind samples required (i.e., a maximum of 400 blind samples per year) in Section 10.1(b). The commenters indicated that for a large agency, there is a very large difference between 3% and 400 samples and suggested keeping only the 3% requirement. Another commenter disagreed with the 3% requirement for blind samples and requested that the amount to be lowered to 1% to lessen the burden on employers. The Department has evaluated the comments and has concluded that no change is needed. The 400 sample limit was added to reduce the burden on large agencies based on the Department's review of agencies' blind testing programs.

One commenter suggested that the wording be modified to clarify that employers are responsible for ensuring blind samples are sent to the laboratories, but that collectors are tasked with submitting the blind samples. The Department has evaluated the comment and has concluded that no change is needed. The wording in Section 10.1(a) clearly describes the responsibilities of the federal agency and the role of the collector in blind sample submission; however, the Department reworded Section 10.3(a) for clarity as described below.

10.3 How is a blind sample submitted to an HHS-certified laboratory?

The Department has reworded Section 10.3(a) to clarify that the collector sends a blind sample to a laboratory as a split specimen (i.e., specimens A and B).

Subpart K – Laboratory

11.9 What are the requirements for an initial drug test?

One commenter noted that HHS previously required initial and confirmatory testing using different techniques, and asked whether this requirement had been removed with allowance of technologies other than immunoassay for initial testing. The commenter expressed concern that an error in the initial drug test could be repeated in the confirmatory drug test using the same method. The Department has evaluated the comment and has concluded that no change is needed. The Guidelines maintain the requirement for initial and confirmatory tests on two separate aliquots to report a result other than negative. The NLCP will review validation and quality control records, as well as specimen records, to ensure that the initial and confirmatory testing methods meet Guidelines requirements and provide scientifically and forensically supportable results.

11.10 What must an HHS-certified laboratory do to validate an initial drug test?

One commenter noted that Section 11.10 provides general information on validation requirements, and asked where detailed requirements can be found. The Department has evaluated the comment and has concluded that no change is needed. The Department will continue to provide details for applicant and certified test facilities through the NLCP.

One commenter asked whether the requirement in 11.10(c) for periodic verification of “each initial drug test using an alternate technology” applied to immunoassay tests used differently than originally cleared by the FDA or other laboratory developed tests. The Department has evaluated the comment and has concluded that no change is needed. This section clearly

distinguishes initial tests using immunoassay from those using an alternate technology.

Furthermore, Section 1.5 includes the definition for “alternate technology initial drug test.”

11.11 What are the batch quality control requirements when conducting an initial drug test?

Seven commenters disagreed with the requirement for an initial test control targeted at 25% above the cutoff. The commenters noted that drug concentrations are much lower in oral fluid than in urine, and stated that assays are unlikely to perform robustly with current immunoassay technology. One commenter also noted that oral fluid is diluted three- to four-fold. One commenter suggested requiring a control targeted at 50% above the cutoff, consistent with current FDA-cleared assays. The Department has evaluated the comments and has concluded that no change is needed. Consistent with the urine program requirements, laboratories must have the ability to apply the program cutoffs to regulated specimens, and document that ability by analyzing a control targeted at 25% above the cutoff in each batch.

One commenter asked whether the inclusion of “additional compounds as target analytes” for amphetamine and opioid assays affect quality control content requirements. The Department has evaluated the comment and has concluded that no change is needed. The initial drug test quality control requirements in the Guidelines apply to each analyte used to calibrate the test (i.e., immunoassay or alternate technology initial drug test). When a single immunoassay test is used for two or more analytes in a drug class, the HHS-certified laboratory must include a control in accordance with item 11.11(a)(2) for each analyte that has less than 100% cross-reactivity with the assay, to demonstrate that the requirement for at least 80% cross-reactivity has been met.

11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

One commenter stated that analyzing quality control samples with concentrations of a drug or metabolite targeted at less than 40% of the proposed cutoffs would be an analytical challenge for high volume laboratories utilizing GC/MS or LC/MS/MS. The Department has evaluated the comments and has concluded that no change is needed. The NLCP Pilot PT Program has documented the capability of laboratories to meet the proposed OFMG requirements.

Also in regard to the proposed quality control requirements for an initial drug test in Section 11.11 and for a confirmatory drug test in Section 11.14, one commenter requested clarification for the requirement for a drug-free control (i.e., whether the control should contain no drug or whether the control should not contain the specific analyte for that test). The Department has evaluated the comment and has concluded that no change is needed. These Guidelines sections list the requirement for “at least one control certified to contain no drug or drug metabolite,” meaning that the control must contain no regulated drug analytes.

11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

The Department has reworded Section 11.15(a) for clarity, to correctly reflect requirements.

11.17 What are the requirements for an HHS-certified laboratory to report a test result?

One commenter suggested that the Department remove the requirement for an executed CCF as the official report for “non-negative” specimens and permit the use of an electronic report with the required information. The Department has evaluated the comment and has concluded

that no change is needed. The Federal CCF establishes the chain of custody for the specimen from the time of collection until receipt by the laboratory and also contains the certification statement signed by the certifying scientist. The Federal CCF may be paper or electronic.

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 11.17 has been revised accordingly.

11.21 What HHS-certified laboratory information is available to a federal agency?

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. The list of items provided in a standard documentation package for an oral fluid specimen has been revised accordingly [i.e., Section 11.21(b)(4)].

11.22 What HHS-certified laboratory information is available to a federal employee?

One commenter asked why the proposed Guidelines include a requirement for a copy of the semiannual statistical summary report to be sent to the Secretary or designated HHS representative. The Department included the requirement to facilitate compilation of statistical information for the federal drug-free workplace program. This will not place an additional burden on the laboratory other than transmission of the report. The Department will continue to evaluate the effectiveness of this requirement.

Subpart L – Instrumented Initial Test Facility (IITF)

12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

One commenter disagreed with prohibiting IITFs for oral fluid. This commenter considers the current HHS-certified urine IITF to be a success in Canada and stated that prohibiting oral fluid IITFs would result in less enthusiasm for regulated procedures and impact workplace safety. At this time, as stated in the preamble to the proposed OFMG, IITFs are not practical and will not be allowed due primarily to the limited specimen volume of oral fluid collected from the donor. The Department will continue to monitor developments in oral fluid drug testing after this new specimen type has been implemented in federal workplace programs, and may reassess the feasibility of allowing IITFs for oral fluid in the future.

Subpart M - Medical Review Officer (MRO)

13.1 Who may serve as an MRO?

Three commenters disagreed with the term “nonmedical use of a drug” used in Section 13.1 (and defined in Section 1.5) and indicated that the term changes the role of an MRO from review, verify and “report a non- negative result” to review, verify and “interpret before reporting a result as negative or nonmedical use of a drug.” Two commenters disagreed with use of “interpretation of results” to supplant “alternative medical explanation.” One commenter noted that this perceived change in the MRO’s role represents an unjustified shifting of risk to the MRO. One commenter believes the term presents a possible legal flaw to Guidelines, stating that this term is legally different from “safety concern” and places MROs in the position of being in conflict with the prescribing physician and subject to lawsuits. This commenter stated that

even a lack of a finding of nonmedical use could be an issue if the donor subsequently had an accident after using the drug. The same commenter submitted five recommendations related to inclusion of prescription drugs in federal workplace drug testing programs, to address the commenter's concerns with the proposed Guidelines. These five specific recommendations pertain to matters that are outside the scope of these Guidelines, and therefore are not addressed in the Department's response below.

The responsibilities of an MRO to interpret results have largely remained the same between the Guidelines effective October 1, 2010 (73 FR 71858) and these Guidelines. As stated in Section 13.5(c) of these Guidelines, "if the donor provides a legitimate medical explanation (e.g., a valid prescription) for the positive result, the MRO reports the test result as negative to the agency." Accordingly, the intent of the Guidelines, in this context, is to confirm whether a positive drug test is the result of drug use under a valid prescription. Furthermore, the term "alternate medical explanation" has never been used in the Guidelines, but has been used in the HHS Medical Review Officer Manual for Federal Workplace Drug Testing Programs.

For the reasons above, the Department believes that the definition of "nonmedical use of a drug" and the requirement for a physician serving as an MRO to have knowledge of this topic do not fundamentally change the MRO's responsibilities. However, to address the commenters' concerns, the Department has removed this term from the Guidelines (i.e., revised Sections 1.5 and 13.1).

One commenter requested clarification that it is the federal agency's burden to ensure that the MRO is certified. One commenter asked how the laboratory will be informed that an MRO has met requirements for re-qualification. The Department evaluated the comments and concluded that no change is needed. The MRO is an employee or a contractor of the agency. Therefore, it

is the agency's responsibility to ensure that the MRO meets the Guidelines qualification requirements.

Two commenters disagreed with the requirement for MRO recertification every five years, and recommended that MROs complete training every three years. Five commenters stated support for five year requalification and examination requirements. The Department has evaluated the comments and has concluded that no change is needed. The Department will keep the five-year requalification requirement as proposed. This is consistent with the MRO requalification requirement in the UrMG.

13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

One commenter agreed with MRO certification/training entities submitting the delivery method and content of the MRO examination as applicable along with other required documents. One commenter agreed with extending time from one to two years for approved MRO certification/training entities' resubmission of qualifications for HHS approval. The commenter noted that they would support further extension to 3 years.

One commenter recommended that approval of MRO educational courses and content be at the discretion of the MRO certification entities, not HHS. Since the certification entities and their examinations are subject to HHS oversight and approval, the commenter noted that it may be burdensome for HHS to review and approve the courses and content, and be a disincentive to development of new courses. One commenter recommended that examinations be allowed to be in-person or online with appropriate security precautions for each delivery method. The Department has evaluated the comments and agrees that the submission of training materials to

HHS would possibly discourage the development of new training courses. Therefore, the review of MRO educational courses and content will not be part of the approval process for MRO certification entities. As described under *Medical Review Officer (MRO) requalification - continuing education units (CEUs)* in this preamble, the Department has removed references to MRO training entities in Section 13.2, because training documentation is maintained by MRO certification entities. The Department will only require the MRO certification entities to submit their examination and any other necessary supporting examination materials (e.g., answers, examination statistics or background information on questions) that will help in the Department's evaluation of the examination. The Department has revised Section 13.2 accordingly.

The Department will review and evaluate the examination delivery method (e.g., in-person or online) when reviewing submitted materials to ensure that the delivery method employs appropriate security and identification procedures.

13.3 What training is required before a physician may serve as an MRO?

Five commenters disagreed and one commenter agreed with the added requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. The Department has evaluated the comments and has revised Section 13.3 to remove this requirement. Federal agencies may provide this information to employees and applicants to facilitate their access to effective treatment and support recovery. The Department provides information to the public on help and treatment for substance misuse and abuse, and how to access those services, on the SAMHSA website <http://www.samhsa.gov/>.

One commenter stated that the Department should add a requirement for MRO training on what constitutes a refusal to test. One commenter suggested that the Department should add a

requirement for MRO training on when and how to report safety concerns to employers when prescription and/or over-the-counter medications may affect performance. The Department has evaluated the comments and has concluded that no change is needed. Criteria for reporting a refusal to test are covered under the topics listed in Section 13.3 such as items (a)(4) training on the Guidelines and (a)(5) procedures for interpretation, review, and reporting of results. When a donor provides a legitimate medical explanation for a positive drug test (e.g., a valid prescription), the Guidelines do not require MROs to contact federal agency employers for the purpose of reporting a safety concern. Accordingly, MRO training related to reporting “safety concerns” does not relate to a mandatory function under the Guidelines and, therefore, is not an essential component of required MRO training. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

In addition, the Department revised Section 13.3 as described under *Medical Review Officer (MRO) requalification - continuing education units (CEUs)* in this preamble. The Department removed references to MRO training entities because training documentation is maintained by MRO certification entities, and added item 13.3(b) to require MRO training on revised Guidelines prior to their effective date.

13.4 What are the responsibilities of an MRO?

One commenter suggested creating a subset of medical professionals trained specifically to determine fitness for duty since an MRO cannot determine fitness for duty over the telephone. The Department has evaluated the comment and has concluded that no change is needed. Fitness for duty evaluations fall outside the purview of the Guidelines.

13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

The Department has revised Section 13.5(c)(1) to include “a valid prescription” as an example of documentation to support a medical explanation for a positive drug test result.

As described under *Testing for Marijuana Use* in this preamble, the Department has revised Section 13.5(c)(1) to reflect the Department's policy that passive exposure to a drug (e.g., exposure to secondhand marijuana smoke) and ingestion of food products containing marijuana are not legitimate medical explanations for a positive drug test result.

In Section 13.5(c)(2)(i), the Department clarified that the requirement for “clinical evidence of illegal use” does not apply if the laboratory confirms the presence of 6-acetylmorphine (i.e., the presence of this metabolite is proof of heroin use).

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

One commenter requested definition of “appropriate expertise” in medical issues raised by a donor's failure to provide a specimen. The same commenter requested medical referral information on the employer's actions when a donor could not provide a urine specimen and then could not provide an oral fluid specimen. The Department has evaluated the comments and has concluded that no change is needed. A physician who is a trained MRO will have the knowledge necessary to identify another physician with appropriate expertise for the medical evaluation. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs as appropriate when oral fluid is allowed in federal workplace drug testing programs.

The Department clarified the definition of “permanent or long-term medical conditions” in Section 13.6(b)(1) based on a federal agency comment.

Subpart O – Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The Department revised wording in items a and b of this section, and included three additional fatal flaws as items f-h, to reflect fatal flaws for regulated donor specimens that have been identified by HHS-certified laboratories. These fatal flaws were addressed in NLCP guidance sent to all HHS-certified and applicant laboratories and IITFs on August 9, 2016. In addition, the Department revised this section to include an additional item i to allow a laboratory to reject a specimen when they identify a flaw that prevents testing or affects the forensic defensibility of the drug test, and cannot be corrected. This general item enables laboratories to reject specimens with fatal flaws that may be rare, but do occur. It is not possible to list all such flaws in the Guidelines.

15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

Two commenters indicated that inclusion of some items as insignificant discrepancies contradicts guidance provided to HHS-certified laboratories and IITFs in NLCP Notices, which required laboratories to attempt to recover missing information. One of these commenters suggested that if these items are important, they should be removed from the “insignificant” list. Two commenters disagreed with the Guidelines designating the listed omissions and

discrepancies as “insignificant only when they occur no more than once per month.” The Department has evaluated the comments. The listed discrepancies would not result in rejection or cancellation. NLCP Notices requiring laboratory action are consistent with this section. However, the Department has reworded section 15.3 to not classify these errors as insignificant. While these types of errors do not warrant laboratory rejection of a specimen or MRO cancellation of a test, as noted in section 15.3(c), corrective action must be initiated when they occur more than once a month.

The commenters indicated that this section implies that the MRO must keep a log of insignificant errors by laboratory and by collection site in order to track frequency. The commenters noted that this is an unenforceable policy, that this should be a duty of inspectors of laboratories and collection sites, and that requiring MROs to keep these types of logs would create significant extra costs. One commenter suggested that item 15.3(c) be modified for the MRO to advise the collector or laboratory to retrain staff on relevant procedures to ensure that collections are completed correctly (rather than directing them to immediately take corrective action). The Department has evaluated the comments and has concluded that no change is needed. This section is the same as in the Guidelines effective October 1, 2010 (73 FR 71858).

One commenter suggested modifying 15.3(a)(5) to read “donor identification number” which would include a social security number or an employee identification number since many employers no longer use social security numbers for employee identification. The Department agrees and has revised Section 15.3(a)(5) to include “employee identification number” in addition to “Social Security Number.”

15.4 What discrepancies may require an MRO to cancel a test?

One commenter suggested adding the scenario where the donor did not sign the CCF because the collector forgot to ask the donor to sign, rather than the donor's refusal to sign. The Department has evaluated the comment and has concluded that no change is needed. As stated in Section 15.4, the MRO contacts the collector "to obtain a statement to verify that the donor refused to sign the MRO copy."

Regulatory Impact and Notices

Executive Order 12866

The Secretary has examined the impact of the Guidelines under Executive Order 12866, which directs federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). In addition, the Department published a Federal Register notice in June 2011 to solicit comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086].

According to Executive Order 12866, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for "a matter relating to agency management or personnel" 5 U.S.C. § 553(a)(2). Because the Guidelines issued by the Secretary

govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a “matter relating to agency management or personnel” and, thus, are not subject to the APA’s requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the May 15, 2015 Federal Register Notice for the proposed OFMG (80 FR 28054), and requested public comment on all estimates and assumptions.

One commenter disagreed with the Department’s projected numbers of oral fluid and urine drug tests by federal agencies and industries regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC). This commenter predicted that there will be a large shift from urine to oral fluid testing when oral fluid is allowed in regulated testing, stating that the oral fluid collection is a more efficient and direct process for the collector, oral fluid is much less likely to be adulterated than urine, oral collections are quicker than most urine collections, and oral fluid is looked upon favorably from a hygienic perspective by donors and collectors. The commenter did not provide any substantive evidence or data to support these comments. One commenter disagreed with inclusion of cost estimates within the Guidelines due to the difficulty in comparing urine and oral fluid costs. The Department has evaluated the comments and has concluded that no change is needed. The Department’s projections were developed using information from current HHS-certified urine testing laboratories, with input from DOT and NRC, and cost analysis was based on information provided by multiple oral fluid testing laboratories and MROs. Each federal agency will decide whether to collect urine, oral fluid, or both specimen types in their workplace testing programs, and DOT and NRC will

decide whether to allow oral fluid testing in workplace drug testing regulations for their regulated industries. Costs are expected to vary among individual laboratories and MROs, depending on their processes and testing populations. Additional information on the estimated costs associated is below.

Need for regulation

Enhances Flexibility

The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) revise the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988, while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results. Urine testing is subject to issues related to a donor's inability to produce a urine specimen due to a legitimate medical condition. In such situations, the test may produce an invalid result or create delays accruing from the need to reschedule the test or medically assess the donor's inability to provide a urine sample. When the OFMG are implemented by an agency, such agency will be authorized to collect an oral fluid specimen from an individual who is unable to provide a urine specimen. This added flexibility will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a specimen. Therefore, the OFMG provide flexibility to address workplace drug testing needs of federal agencies by permitting the selection of the specimen type best suited for their needs and authorizing collection of an alternative specimen type when a donor is unable to provide a specimen. The

added flexibility will also benefit donors, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

Enhances Versatility

Urine collection requires use of a specialized collection facility, secured restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings. An acceptable oral fluid collection site must allow the collector to observe the donor, maintain control of the collection device(s) during the process, maintain record storage, and protect donor privacy.

Decreases Invalid Tests

All unobserved specimen collections are at risk for substitution and adulteration. Studies conducted by the drug testing industry indicate that 0.05 to 3% of urine specimens collected for drug use detection are determined to be substituted or adulterated.^{5,27,28} Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. Specimen validity testing of oral fluid specimens will be allowed to identify invalid specimens (e.g., testing for a biomarker such as albumin or immunoglobulin G, IgG).

Saves Time

Oral fluid collection can require less time than urine collection, reducing employee time away from the workplace and, therefore, reducing costs to the federal agency employer. Oral fluid collection does not require a facility that provides visual privacy during the collection.

Unlike urine specimen collections, it is expected that many oral fluid collections will occur at or near the workplace, and not at a dedicated collection site, thereby reducing the amount of time away from the workplace. The collector is allowed to be in the vicinity of the donor, reducing the loss of productive time. The option to collect a urine specimen in the event that the donor cannot provide an oral fluid specimen (and vice versa) will reduce both the need to reschedule a collection and the need for the MRO to arrange a medical evaluation of a donor's inability to provide a specimen. Administrative data for urine collections indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be more than 2 hours. This estimate takes into account the time savings if the oral fluid collection was conducted at the employee's workplace, and thus incorporates travel time savings. Using OPM's estimate for the average annual salary of Federal employees converted to an hourly wage, the savings generated for the Federal Government would be roughly \$400,000 to \$1.2 million a year, or \$38 to \$114 per test.

Versatility in Detection

The time course of drugs and metabolites differs between oral fluid and urine, resulting in some differences in analytes and detection times. Oral fluid tests generally are positive as soon as the drug is absorbed into the body. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation. Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected. A federal agency may select the

specimen type for collection based on the circumstances of the test. For example, in situations where drug use at the work-site is suspected, the testing of oral fluid may show the presence of an active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior.

Current Testing in the Drug Free Workplace Program

Urine was the original specimen of choice for forensic workplace drug testing, and urine testing is expected to remain an established and reliable component of federal workplace drug testing programs. Urine testing provides scientifically accurate and legally defensible results and has proven to be an effective deterrent to drug use in the workplace.

A major challenge to urine drug testing has been the proliferation of commercial products used to adulterate or substitute a donor's urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As the Department has established requirements and laboratories have developed procedures to control for adulterated and substituted specimens, manufacturers have developed new products to avoid detection. The use of these products is expected to continue.

Cost and Benefit

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. The Department projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The subsequent transition to oral fluid testing is expected to be gradual and

steady over the course of four years, when it should plateau to account for 25 to 30% of federal agency drug testing (i.e., 37,500 to 45,000 specimens). This transition estimate is based on the non-regulated sector's time course of the testing of oral fluid and urine in the four years preceding the final OFMG.

The approximate annual numbers of regulated specimens collected from applicants and employees under the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) drug testing regulations are 6 million and 155,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and numbers of specimens for NRC would be 10,850 oral fluid and 144,150 urine. Assuming the same four-year transition time for DOT- and NRC-regulated industries, the numbers of oral fluid specimens are expected to be 1,500,000 to 1,800,000 specimens under DOT regulations and 38,750 to 46,500 specimens under NRC regulations.

In Section 3.4, the Department included criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specified the cross-reactivity of the immunoassay to the other analytes(s) within the group. These Guidelines allow the use of methods other than immunoassay for initial testing. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS-certified laboratories currently testing private sector oral fluid specimens. Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the

Department through the NLCP. Estimated laboratory costs to complete and submit the application are \$3,000, and estimated costs for the Department to process the application are \$7,200. These estimates are from SAMHSA and are based on the NLCP fee schedule and historical costs. The initial certification process includes the requirement to demonstrate that the applicant laboratory's performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from \$900 to \$1,800 for each applicant laboratory.

Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between \$108,000 and \$138,000 (i.e., assuming 8 hours of time multiplied by a GS 12/13 wage including benefits and overhead adjustments). This training cost is included in the costs of the revised URMG. The Department will offer the choice of online or in-person training. This will eliminate travel costs for those federal agencies who choose to use online training.

Summary of One-Time Costs

	Lower Bound	Upper Bound	Primary
Cost of Application*	-	-	\$93,000.00
Application Processing*	-	-	\$217,000.00
Performance Testing*	\$27,900.00	\$55,800.00	
Training*	\$108,000.00	\$138,000.00	
Total	\$445,900.00	\$503,800.00	

*Estimated using costs presented above multiplied by the number of

Laboratories (31).
Costs and Benefits

Thus, the Department estimates one-time, upfront costs of between \$446,000 and \$504,000. While the Department has only monetized a small portion of the benefits (time savings) to a small subset of the workplace drug testing programs that could be affected by the OFMG (i.e., federal employee testing programs and not drug testing programs conducted under NRC and DOT regulations), the Department is confident that the benefits would outweigh the costs. Even if NRC and DOT do not implement oral fluid testing for their regulated industries' drug testing programs, the benefits to Federal workplace testing programs, estimated at between \$400,000 and \$1.2 million, would recur on an annual basis.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This set of Guidelines is considered an EO 13771 deregulatory action. The net cost savings, annualized over a perpetual time horizon using a 7% discount rate and expressed in 2016 dollars, is estimated to be \$87.34 million.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that the Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the OFMG will not require additional expenditures. Therefore, a final regulatory flexibility analysis is not required for this notice.

As mentioned in the section on Executive Order 12866, the Secretary anticipates that there will be an overall reduction in costs if drug testing is expanded under the OFMG. The costs to implement this change to regulation are negligible. The added flexibility will permit federal agencies to select the specimen type best suited for their needs and to authorize collection of an

alternative specimen type when an employee is unable to provide the originally authorized specimen type. Insofar as there are costs associated with each drug test, this could lead to lower overall testing costs for federal agencies. The added flexibility will also benefit federal employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

The Secretary has determined that the Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of \$100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the Guidelines do not impose a mandate that results in an expenditure of \$100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The Secretary has considered the environmental effects of the OFMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed the Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, "policies that have federalism implications" refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary establishes standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and

responsibilities among the various levels of government. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

Privacy Act

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The Federal Register notice announcing the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809]. The revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on January 23, 2017 [82 FR 7920] with an effective date of October 1, 2017.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the

development of regulatory policies that have tribal implications.” “Policies that have tribal implications” as defined in the Executive Order, include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.” The Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The information collection requirements (i.e., reporting and recordkeeping) in the current Guidelines (82 FR 7920), which establish the scientific and technical guidelines for federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930-0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930-0158, will remain in effect for regulated urine drug testing under the UrMG. The same

documents specifically for regulated oral fluid drug testing under the OFMG will be submitted for OMB approval under a new control number.

The title, description, and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting, disclosure and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens

Description: The Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100-71, 5 U.S.C. section 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine specimen testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine specimen testing are approved under OMB control number 0930-0158. These Guidelines establish when oral fluid specimens may be collected, the procedures that must be used in collecting an oral fluid specimen, and the certification process for approving a laboratory to test oral fluid specimen.

Description of Respondents: Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

The annual burden estimates in the tables below are based on the following number of respondents: 10,500 donors who apply for employment or are employed in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

Estimate of Annual Reporting Burden

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
9.2(a)(1)	Laboratory required to submit application for certification	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector	10	1	2	20
11.3(a)	Laboratory submits qualifications of RP to HHS	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP	10	1	2	20
11.20	Specifications for laboratory semi-annual statistical report of test results to each federal agency	10	5	0.5	25
13.9 & 14.6	Specifies that MRO must report all verified primary and split specimen test results to the federal agency	100	14	0.05 (3 min)	70
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review	1	1	50	50
16.9(a)	Specifies content of	1	1	3	3

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
	appellant request for expedited review of suspension or proposed revocation				
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
TOTAL		156			292

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or refuse to participate in the collection process on the Federal CCF (sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); MRO notifies the federal agency and HHS when an error occurs on a blind sample (section 10.4(c)); section 13.5 describes the actions an MRO takes to report a primary specimen result; and section 14.5 describes the actions an MRO takes to report a split specimen result. SAMHSA has not calculated a separate reporting burden for these requirements because they will be included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to federal agencies.

Estimate of Annual Disclosure Burden

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
8.3(a) & 8.6(b)(2)	Collector must contact federal agency point of contact	100	1	0.05 (3 min)	5
11.21 & 11.22	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO	50	10	3	1,500
13.8 (b)	MRO must inform donor of right to request split specimen	100	14	3	4,200

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
	test when a positive or adulterated result is reported				
TOTAL		210			5,705

The following disclosure requirements are also included in the Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (section 8.3(f) and (h)), and must review the procedures for the oral fluid specimen collection device used with the donor (section 8.4(b)). The Department believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

Estimate of Annual Recordkeeping Burden

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
8.3, 8.5, & 8.8	Collector completes Federal CCF for specimen collected	100	380	0.07 (4 min)	2,534
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF	10,500	1	0.08 (5 min)	875
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result	10	3,800	0.05 (3 min)	1,900
13.4(d) (4), 13.9 (c), & 14.6(c)	MRO completes Federal CCF before reporting the result	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested	300	1	0.05 (3 min)	15
TOTAL		11,010			7,224

The Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector [section 4.3(a)(3)] and the documentation must be

maintained in the collector's training file [section 4.3(c)]. Because this is required by the current Guidelines using urine specimens as well as these Guidelines using oral fluid specimens and is consistent with general forensic requirements, SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a federal agency specimen, the collector is required to provide a statement [section 6.2(b)] explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H [sections 8.4(d) and 8.5(a)(1)] requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K describe a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (i.e., sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(1); 11.13(a); 11.16; 11.17(a), (b), and (c); 11.20; 11.21, and 11.22. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus, the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,221 hours (that is, the sum of the total hours from the above tables). Because of the expected transition from urine to oral fluid testing, this number will

replace some of the 1,788,809 hours currently approved by OMB under control number 0930-0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of the proposed Guidelines to OMB for its review. Comments on the information collection requirements were specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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Dated: October 7, 2019.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and
Substance Use.

Dated: October 7, 2019.

Alex M. Azar II,
Secretary,
Department of Health and Human Services.

The Mandatory Guidelines using Oral Fluid Specimens are hereby adopted in accordance with section 503 of Public Law 100-71 and Executive Order 12564.

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING ORAL FLUID SPECIMENS

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Subpart A - Applicability

Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees,

detainees, probationers, incarcerated persons, or parolees.¹

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100-71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a federal agency request a change from these Guidelines?

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of

¹ The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR Part 26, “Fitness for Duty Programs” (i.e., employees of certain NRC-regulated entities).

¹ Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that “incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988 and any amendments to those guidelines...” See, e.g., 49 U.S.C. §20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR Part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR §40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) The changes will be published in final as a notice in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor

specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (e.g., drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Device. A product that is used to collect an oral fluid specimen and may

include a buffer or diluent.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (e.g., drug or drug metabolite concentration) used as the decision point to determine a result (e.g., negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (i.e., HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper

(hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.7 when a positive or negative result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (e.g., drug or drug metabolite) can be identified.

Limit of Quantification. For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (e.g., drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (e.g., reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance

characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmation cutoff concentration.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2)

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Oral Fluid). A collection in which two specimens [primary (A) and split (B)] are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101-24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100-71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable

Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR Parts 160 and 164, Subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit <http://www.hhs.gov/ocr/hipaa>.

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(3) Fail to provide a specimen (e.g., oral fluid or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations with the exception of a

donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(4) Fail to provide a sufficient amount of oral fluid when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(5) Fail or decline to participate in an alternate specimen collection (e.g., urine) as directed by the federal agency or collector (i.e., as described in Section 8.6);

(6) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (i.e., Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(7) Fail to cooperate with any part of the testing process (e.g., disrupt the collection process; fail to rinse the mouth after being directed to do so by the collector; refuse to provide a split specimen);

(8) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(9) Attempt to adulterate, substitute, or dilute the specimen; or

(10) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test except a pre-employment test as described in Section 1.7(a)(1), the collector must terminate the collection process and take action as described in Section 8.9. Required action includes immediately notifying the federal agency's designated representative by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

- (1) Checking the refusal to test box;
- (2) Providing a reason for the refusal in the remarks line; and
- (3) Signing and dating the MRO copy of the Federal CCF.

Subpart B - Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A federal agency may collect an oral fluid specimen for the following reasons:

- (a) Federal agency applicant/Pre-employment test;
- (b) Random test;
- (c) Reasonable suspicion/cause test;
- (d) Post accident test;
- (e) Return to duty test; or
- (f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (i.e., collected either simultaneously or serially) as described in Sections 2.5 and 8.8.

Section 2.4 What volume of oral fluid is collected?

A volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated “Tube A” and “Tube B”) is collected using a collection device. If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1

mL.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as “A” (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as “B” (split) either simultaneously or serially (i.e., using two devices or using one device and subdividing the specimen), as described in Section 8.8.

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1, may not release specimens collected pursuant to Executive Order 12564, Public Law 100-71 and these Guidelines, to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor’s request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C – Oral Fluid Drug and Specimen Validity Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A federal agency:

- (a) Must ensure that each specimen is tested for marijuana and cocaine as provided under Section 3.4;
- (b) Is authorized to test each specimen for opioids, amphetamines, and phencyclidine, as

provided under Section 3.4; and

(c) Is authorized upon a Medical Review Officer's request to test an oral fluid specimen to determine specimen validity using, for example, a test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(d) If a specimen exhibits abnormal characteristics (e.g., unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (e.g., non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for additional drugs?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing

for approval to routinely test for any drug class not listed in Section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees or any other entity, for other purposes (e.g., deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?

Initial Test Analyte	Initial Test Cutoff ¹	Confirmatory Test Analyte	Confirmatory Test Cutoff Concentration
Marijuana (THC) ²	4 ng/mL ³	THC	2 ng/mL
Cocaine/ Benzoyllecgonine	15 ng/mL	Cocaine Benzoyllecgonine	8 ng/mL 8 ng/mL
Codeine/ Morphine	30 ng/mL	Codeine Morphine	15 ng/mL 15 ng/mL
Hydrocodone/ Hydromorphone	30 ng/mL	Hydrocodone Hydromorphone	15 ng/mL 15 ng/mL

Oxycodone/ Oxymorphone	30 ng/mL	Oxycodone Oxymorphone	15 ng/mL 15 ng/mL
6-Acetylmorphine	4 ng/mL ³	6-Acetylmorphine	2 ng/mL
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL
Amphetamine/ Methamphetamine	50 ng/mL	Amphetamine Methamphetamine	25 ng/mL 25 ng/mL
MDMA ⁴ /MDA ⁵	50 ng/mL	MDMA MDA	25 ng/mL 25 ng/mL

¹For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

²An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol (THC).

³**Alternate technology (THC and 6-AM):** The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for THC, 2 ng/mL for 6-AM).

⁴ Methylenedioxymethamphetamine (MDMA)
⁵ Methylenedioxyamphetamine (MDA)

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (e.g., specimen validity tests including biomarker and/or adulterant tests, tetrahydrocannabinavarin). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

An HHS-certified laboratory reports an oral fluid specimen as adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report an invalid result for an oral fluid specimen?

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

- (a) Interference occurs on the initial drug tests on two separate aliquots (i.e., valid

immunoassay or alternate technology initial drug test results cannot be obtained);

(b) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen (e.g., viscosity) is such that testing the specimen may damage the laboratory's instruments;

(d) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (e.g., color) are clearly different; or

(e) The concentration of a biomarker (e.g., albumin or IgG) is not consistent with that established for human oral fluid for both the initial (first) test and the second test on two separate aliquots.

Subpart D - Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (e.g., fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process,

ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen tube tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a “train the trainer” course given by an organization (e.g., manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer’s training and provide that documentation to a federal agency when requested.

Section 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

Subpart E - Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work

site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (e.g., an accident investigation), another site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

- (a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);
- (b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;
- (c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;
- (d) A restricted access area where only authorized personnel may be present during the collection;
- (e) A restricted access area for the storage of collection supplies; and
- (f) The ability to store records securely.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (e.g., collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering.

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during

transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F - Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the documentation provided by the collector, the HHS-certified laboratory must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that the collector used an incorrect form, the laboratory or MRO must obtain a memorandum for the record from the collector

describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G – Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

An FDA-cleared single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

- (a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;
- (b) A sealable, non-leaking container that maintains the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites;
- (c) Components that ensure pre-analytical drug and drug metabolite stability; and
- (d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

- (a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;
- (b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):
 - (1) The volume of oral fluid collected should be at least 1.0 mL \pm 10 percent, and
 - (2) The volume of diluent in the device should be within \pm 2.5 percent of the diluent target volume;
- (c) Stability (recoverable concentrations \geq 80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64-77 °F/18-25 °C) and under the manufacturer's intended shipping and storage conditions; and
- (d) Recover \geq 80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff (see Section 3.4).

Subpart H – Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

- (a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

- (b) The collector is not required to be the same gender as the donor.

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must deter the adulteration or substitution of an oral fluid specimen at the collection site.

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The collector must take the following steps before beginning an oral fluid specimen collection:

- (a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

- (b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

- (c) The collector requests the donor to present photo identification (e.g., driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (e.g., candy, gum, food, tobacco) or could be used to adulterate, substitute, or dilute the specimen. If an item is present that appears to have been brought to the collection site with the intent to adulterate, substitute, or dilute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(1) At this time, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in Section 8.5.

(2) If the collector's inspection of the donor's oral cavity reveals any items that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva), or the donor claims to have "dry mouth," the collector gives the donor water (e.g., up to 4 oz.) to rinse their mouth. The donor may drink the water. The collector must then wait 10 minutes before beginning the specimen collection. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(e) The collector must provide identification (e.g., employee badge, employee list) if requested by the donor.

(f) The collector explains the basic collection procedure to the donor.

(g) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(h) The collector answers any reasonable and appropriate questions the donor may have

regarding the collection procedure.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector will provide or the donor may select a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The specimen collection device will be opened in view of the donor.

(1) Both the donor and the collector must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(b) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (e.g., an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in step (a)(1) above, refuses to provide a split specimen as instructed by the collector, or refuses to provide an alternate specimen as authorized in Section 8.6, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and

attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor is not required to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (i.e., in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen

type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All federal agency collections are to be split specimen collections.

An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Tube A” and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Tube B”.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the federal agency by means (e.g., telephone, e-mail, or secure fax) that ensures that the notification is immediately received,

- (b) Documenting the refusal to test on the Federal CCF, and
- (c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.10 What are a federal agency's responsibilities for a collection site?

- (a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.
- (b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (e.g., virtual, onsite, or self-evaluation).
- (c) A federal agency must investigate reported collection site deficiencies (e.g., specimens reported "rejected for testing" by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (i.e., using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I - HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (i.e., the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

- (3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;
- (4) Satisfy all the requirements for an initial inspection; and
- (5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory to maintain HHS certification?

- (a) To maintain HHS certification, a laboratory must:
 - (1) Successfully participate in both the maintenance PT and inspection programs (i.e., successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);
 - (2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and
 - (3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

- (a) A laboratory that does not maintain its HHS certification must:
 - (1) Stop testing federally regulated specimens;
 - (2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.7;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance or other substances for special purposes.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) The laboratory must (to the greatest extent possible) handle, test, and report a PT

sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [i.e., no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ± 50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [i.e., no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ± 50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's testing procedures and facilities using an inspection checklist.

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

(a) An HHS-certified laboratory must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K;

(2) Has read and thoroughly understands the policies and requirements contained in these

Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

- (3) Submits a resume and documentation of qualifications to HHS;
 - (4) Attends approved training; and
 - (5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.
- (b) The Secretary or a federal agency may conduct an inspection at any time.

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (e.g., 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's certification is revoked or suspended in accordance with the process described in Subpart P, the laboratory is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (e.g., an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory by a federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and

reliable drug testing.

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

- (1) The reasons for the suspension or proposed revocation;
- (2) The terms of the suspension or proposed revocation; and
- (3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3

days of the date the laboratory received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

- (a) The list of HHS-certified laboratories is published monthly in the **Federal Register**.

This notice is also available on the Internet at <http://www.samhsa.gov/workplace>.

- (b) An applicant laboratory is not included on the list.

Subpart J - Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection device as to their content using appropriate initial and confirmatory tests.

- (1) Drug positive blind samples must be fortified with one or more of the drugs or

metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (i.e., certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with

the expected result (e.g., a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K - Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP

manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

- (1) Chain of custody procedures;
- (2) Accessioning;
- (3) Security;
- (4) Quality control/quality assurance programs;
- (5) Analytical methods and procedures;
- (6) Equipment and maintenance programs;
- (7) Personnel training;
- (8) Reporting procedures; and
- (9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing

their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research

experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (e.g., publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (e.g., temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility,

specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (i.e., for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (e.g., firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What are the requirements for an initial drug test?

- (a) An initial drug test may be:
 - (1) An immunoassay or
 - (2) An alternate technology (e.g., spectrometry, spectroscopy).
- (b) An HHS-certified laboratory must validate an initial drug test before testing specimens.
- (c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.
- (d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

- (a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:
 - (1) The ability to differentiate negative specimens from those requiring further testing;
 - (2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;
 - (3) The effective concentration range of the test (linearity);
 - (4) The potential for carryover;
 - (5) The potential for interfering substances; and
 - (6) The potential matrix effects if using an alternate technology.
- (b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

- (a) Each batch of specimens must contain the following controls:
 - (1) At least one control certified to contain no drug or drug metabolite;
 - (2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;
 - (3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and
 - (4) At least one control that appears as a donor specimen to the analysts.
- (b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.12 What are the requirements for a confirmatory drug test?

- (a) The analytical method must use mass spectrometric identification [e.g., gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.
- (b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.
- (c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

- (1) The linear range of the analysis;
- (2) The limit of detection;
- (3) The limit of quantification;
- (4) The accuracy and precision at the cutoff concentration;
- (5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;
- (6) The potential for interfering substances;
- (7) The potential for carryover; and
- (8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

- (1) A calibrator at the cutoff concentration;
- (2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid or adulterated specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5

working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (e)(1) through (e)(4) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) For a specimen that has an invalid result for one of the reasons stated in items (e)(1) through (e)(4) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(e) A primary (A) oral fluid specimen is reported as an invalid result when:

(1) Interference occurs on the initial drug tests on two separate aliquots (i.e., valid initial drug test results cannot be obtained);

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(3) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(4) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(5) The concentration of a biomarker (e.g., albumin or IgG) is not consistent with that established for human oral fluid.

(f) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all positive, adulterated, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(i) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than “insert the actual value for the upper limit of the linear range,” or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method’s linear range and multiplying the result by the appropriate dilution factor.

(k) HHS-certified laboratories may transmit test results to the MRO by various electronic means (e.g., teleprinter, facsimile, or computer). Transmissions of the reports must ensure

confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(l) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(m) For positive, adulterated, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (-20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.19 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for

storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or e-mail within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

- (1) Reporting period (inclusive dates);
- (2) HHS-certified laboratory name and address;
- (3) Federal agency name;
- (4) Number of specimen results reported;
- (5) Number of specimens collected by reason for test;
- (6) Number of specimens reported negative;

- (7) Number of specimens rejected for testing because of a fatal flaw;
- (8) Number of specimens rejected for testing because of an uncorrected flaw;
- (9) Number of specimens tested positive by each initial drug test;
- (10) Number of specimens reported positive;
- (11) Number of specimens reported positive for each drug and drug metabolite;
- (12) Number of specimens reported adulterated; and
- (13) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.21 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive or adulterated drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.22 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.21(b) and

any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines.

Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart L – Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

No, only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

Subpart M - Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

- (a) A currently licensed physician who has:
 - (1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;
 - (2) Knowledge regarding the pharmacology and toxicology of illicit drugs;
 - (3) The training necessary to serve as an MRO as set out in Section 13.3;
 - (4) Satisfactorily passed an initial examination administered by a nationally recognized entity or subspecialty board that has been approved by the Secretary to certify MROs; and
 - (5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (e.g., answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and

content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at <http://www.samhsa.gov/workplace/drug-testing>.

Section 13.3 What training is required before a physician may serve as an MRO?

- (a) A physician must receive training that includes a thorough review of the following:
 - (1) The collection procedures used to collect federal agency specimens;
 - (2) How to interpret test results reported by HHS-certified IITFs and laboratories (e.g., negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);
 - (3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;
 - (4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and
 - (5) Procedures for interpretation, review (e.g., donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;
- (b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(d) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of 2 years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive or adulterated result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.5(c).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides documentation (e.g., a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(i) Passive exposure to a drug (e.g., exposure to secondhand marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing marijuana is not a legitimate medical explanation for a positive drug test result.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL and no legitimate medical explanation: the MRO must determine if there is clinical evidence of illegal use (in addition to the drug test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (i.e., the presence of this metabolite is proof of heroin use).

(ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation: the MRO reports a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the oral fluid specimen was adulterated.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (e.g., a prescription medication), the

MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result with the reason for the invalid result and directs the agency to collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (e.g., urine).

(f) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

(a) When another specimen type (e.g., urine) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who

has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of

oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (e.g., urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (i.e., authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test

because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (e.g., urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This

report must state that a permanent or long-term medical condition [as defined in Section 13.6 (b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (e.g., the federal agency is not authorized to allow the donor to begin or resume performing official functions because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive or adulterated result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (e.g., teleprinter, facsimile, or computer).

Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access

to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart N - Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (i.e., second) HHS-certified oral fluid laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (e.g., insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) oral fluid specimen as:

(a) Reconfirmed the drug(s) or adulteration result. The MRO reports reconfirmed to the agency.

(b) Failed to reconfirm a single or all drug positive results and adulterated. If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm [specify drug(s)] and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm [specify drug(s)] and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency

to immediately collect another specimen. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) Failed to reconfirm a single or all drug positive results and not adulterated. The MRO reports to the agency a failed to reconfirm result [specify drug(s)], cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(d) Failed to reconfirm a single or all drug positive results and invalid result. The MRO reports to the agency a failed to reconfirm result [specify drug(s) and give the reason for the invalid result], cancels both tests, directs the agency to immediately collect another specimen and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen

(f) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to

reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) Failed to reconfirm adulteration. The MRO reports to the agency a failed to reconfirm result (specify adulterant) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) Failed to reconfirm a single or all drug positive results and reconfirmed an adulterant. The MRO reports to the agency a reconfirmed result (specify adulterant) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed result (adulterated) although Laboratory B failed to reconfirm the drug(s) result.

(j) Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterant. The MRO reports to the agency a failed to reconfirm result [specify drug(s) and adulterant] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) Failed to reconfirm at least one drug and reconfirmed the adulterant. The MRO reports to the agency a reconfirmed result [specify drug(s) and adulterant] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the reconfirmed adulterant although Laboratory B failed to reconfirm one or more drugs.

(l) Failed to reconfirm at least one drug and failed to reconfirm the adulterant. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result

[specify drug(s) and adulterant]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterant.

Section 14.6 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (e.g., teleprinter, facsimile, or computer).

Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

Section 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for

the primary (A) specimen.

Subpart O - Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory without a CCF;

(g) The CCF was received at the HHS-certified laboratory without a specimen;

- (h) The collector performed two separate collections using one CCF; or
- (i) The HHS-certified laboratory identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to

reject an oral fluid specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

- (1) An incorrect laboratory name and address appearing at the top of the form;
- (2) Incomplete/incorrect/unreadable employer name or address;
- (3) MRO name is missing;
- (4) Incomplete/incorrect MRO address;
- (5) A transposition of numbers in the donor's Social Security Number or employee identification number;
- (6) A telephone number is missing/incorrect;
- (7) A fax number is missing/incorrect;
- (8) A "reason for test" box is not marked;
- (9) A "drug tests to be performed" box is not marked;
- (10) A "specimen collection" box is not marked;
- (11) The lot number of the collection device used for the collection is missing;
- (12) The collection site address is missing;
- (13) The collector's printed name is missing but the collector's signature is properly recorded;
- (14) The time of collection is not indicated;
- (15) The date of collection is not indicated;
- (16) Incorrect name of delivery service;
- (17) The collector has changed or corrected information by crossing out the original

information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P - Laboratory Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of the official's employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review

has been filed, the appellant shall notify the reviewing official at the end of the abeyance period, advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) Appellant's Documents and Brief. Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) Respondent's Documents and Brief. Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or

revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) Reply Briefs. Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) Cooperative Efforts. Whenever feasible, the parties should attempt to develop a joint review file.

(e) Excessive Documentation. The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) Electing Oral Presentation. If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) Presiding Official. The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) Preliminary Conference. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at their discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) Time and Place of the Oral Presentation. The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) Conduct of the Oral Presentation.

(1) General. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) Burden of Proof/Standard of Proof. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) Admission of Evidence. The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) Obstruction of Justice or Making of False Statements. Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) Post-hearing Procedures. At their discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each

party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) Applicability. When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) Reviewing Official's Response. As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) Review File and Briefs. Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) Oral Presentation. If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place

determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) Written Decision. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) Transmission of Written Communications. Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) Issuance of Decision. The reviewing official shall issue a written decision upholding

or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) Date of Decision. The reviewing official will attempt to issue their decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) Public Notice. If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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